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RADIATION HEALTH AND SAFETY

HEARINGS

BEFORE THE

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

UNITED STATES SENATE

NINETY-FIFTH CONGRESS

FIRST SESSION

ON

OVERSIGHT OF RADIATION HEALTH AND SAFETY

JUNE 16, 17, 27, 28 AND 29, 1977

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RADIATION HEALTH AND SAFETY

THURSDAY, JUNE 16, 1977

U.S. Senate,
Committee on Commerce, Science, and Transportation,
Washington, D.C.

The committee met at 10 a.m. in room 5110 of the Dirksen Senate Office Building, Hon. Wendell H. Ford presiding.

OPENING STATEMENT BY SENATOR FORD

Senator Ford. Good morning, ladies and gentlemen. May I have your attention, please.

Today we convene comprehensive oversight hearings on the subject of radiation health and safety. Our objectives in holding these hearings are several. First, the committee is concerned with the ever-increasing number of radiation-emitting devices in the environment. It has been proven that where these devices are not adequately controlled and protection of human health provided, ionizing radiation can cause severe damage. Furthermore, experts have raised questions about the effects of nonionizing radiation. Since every man, woman, and child in the country is exposed daily to manmade sources of radiation, we have a very important obligation to see that adequate steps are being taken to determine any potential health hazards and to provide adequate safeguards to prevent any hazards.

The committee has never before been in a better position to examine the total radiation health and safety picture. Since this committee was in large part responsible for the enactment of the Radiation Control for Health and Safety Act of 1968, we are interested in determining how the act has been implemented. In addition, under the recent reorganization of Senate committees, the Committee on Commerce, Science, and Transportation has comprehensive oversight jurisdiction over all policy matters relating to science, engineering, and technology research and development.

Our intention, then, is to make these hearings the most comprehensive ever held on this issue. In its preliminary work, data was solicited from 32 different Federal agencies relative to their research and regulatory efforts. We also requested their expert opinions on the adequacy of present Federal efforts in this area.

A careful examination of this preliminary data indicates the potential exists for confusion, overlap, and duplication of effort at the Federal level in both research and regulation. The committee is interested in seeing what may be done to coordinate or clarify these responsibilities to insure that the public's interest is best served.

In addition, the committee is aware of present public concern over many reports concerning radiation effects which have appeared in the media—for example, the controversy surrounding mammography, the microwave irradiation of the Moscow embassy, the Navy's proposed project Seafarer.

The committee is aware of the controversial nature of many of these issues. Nevertheless, these issues justifiably continue to be of significant public interest. Because the committee recognizes the complexity of current scientific opinion, we intend to pursue this inquiry in an objective but vigorous manner. We believe this set of hearings will be but the first step in our investigation and analysis.

The last time the committee held oversight hearings on radiation health and safety was in 1973. Since then, we have seen the emergence of new agencies and reports of new studies in the radiation health and safety field.

However, the committee, as it was in 1973, is still concerned with many of these same issues. As in 1973, there is concern that many of our citizens are exposed unnecessarily to excessive diagnostic X-radiation. The Bureau of Radiological Health indicates it considers the inspection of medical and dental X-ray equipment a priority problem. Further, the Bureau of Radiological Health recognizes that much must be done to assure that X-ray machine operators adhere to proper radiation protection practices.

Another major source of interest to the committee is the increasing proliferation of nonionizing-radiation-emitting devices in the environment. These include not only the microwave ovens which were the focus of the committee's 1973 hearings, but various other communications and defense technologies utilizing this form of radiation. We recognize that radiation utilized in various technologies has tremendous potential for good and holds great significance for the economy, the communications network, national defense, and the healing arts. Although the committee is not interested in sitting as a "science court," it is determined to assure that our increasing reliance on these technologies is accompanied by appropriate research into possible health and environmental effects and, if necessary, that appropriate regulatory standards are implemented. Thus, we intend to hear from many experts in the field who will advise us on the best means of achieving this end.

First, we shall hear from Dr. Stefan Schiff, who will discuss general characteristics and biological effects of ionizing and nonionizing radiation. Also, we are fortunate to have with us here today representatives of the two major agencies having radiation health and safety responsibilities, the Bureau of Radiological Health and the Environmental Protection Agency.

Doctor, you are first. We are happy to have you here this morning to explain to us the subject at hand.

You may proceed.

STATEMENT OF DR. STEFAN O. SCHIFF, GENETICS PROGRAM, DEPARTMENT OF BIOLOGICAL SCIENCES, GEORGE WASHINGTON UNIVERSITY

Dr. SCHIFF. Thank you.

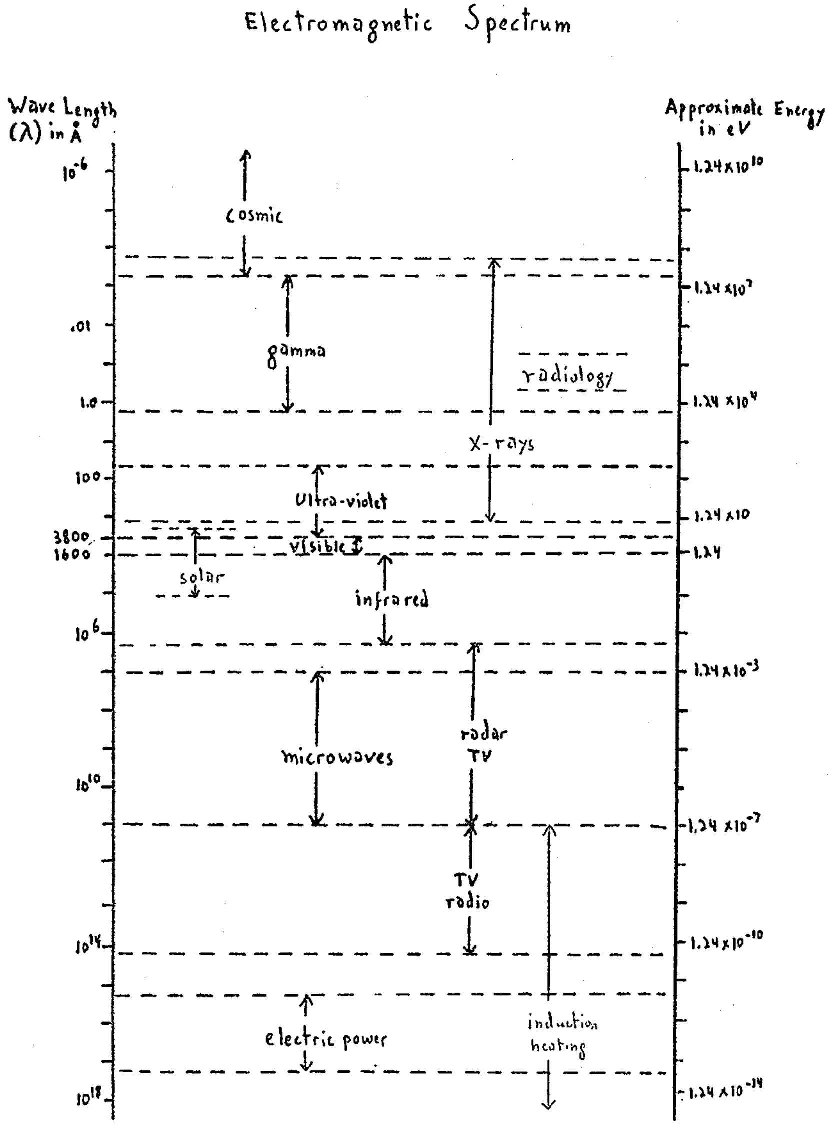
I have never before testified before a Senate subcommittee, so this is a new experience for me. And I am going to follow the written testimony that was distributed fairly closely, but not verbatim.

In the time span allotted, I cannot cover the entire spectrum of different types of radiation, so I plan to concentrate on several, which I will mention as I go. And I want to begin by making a few comments about the——

Senator FORD. Doctor, your prepared testimony to the committee will be included in the record.

Dr. SCHIFF. Thank you. The types of radiation which potentially represent a human hazard cover most of the electromagnetic spectrum. If you will peruse the chart, you will note that the wavelengths are given in the left-hand column. The figures are given in angstrom units, which is 10 to the minus 8 centimeters.

[The chart follows:]



The energy associated with the radiation is given in the right-hand column of the chart, and the amount of radiation is given in electron-volts. Please note that as the energy increases, the wavelength decreases, so that there is an inverse relationship between the two. Radiation that has short wavelengths and high energy as those shown at the top of the chart, like X-rays, gamma rays, cosmic rays, and so on, has the ability to ionize atoms, whereas radiation with longer wavelengths and less energy, like microwaves, radar, and so on, does not have enough energy to produce ionization.

The cutoff is approximately at the upper bar of the ultraviolet light spectrum on the chart. Not shown in the chart are various types of particulate radiation. The electromagnetic spectrum deals only with radiation that doesn't have a mass associated with it. Particulate radiation is the type of radiation that concerns itself with particles that have mass, such as neutrons and alpha rays. All of these would fall into the ionizing radiation category, as opposed to the nonionizing.

Insofar as ionizing radiation is concerned, I want to concentrate primarily on the nonparticulate radiation, especially X and gamma rays because of their widespread use in medicine. They are the most common source of human exposure. Characteristically, such radiation consists of photons—that is, packets of energy, or of continuous waves of energy that travel at approximately the speed of light. They have great penetrating power, and consequently they are able to travel long distances through air or through tissue. The higher their energy, the longer is their path length, and the more deeply they penetrate.

I have indicated the units of measurement of ionizing radiation in the written testimony, and will not repeat them here.

Insofar as the mode of action of the radiation is concerned, the energy associated with the ionizing radiation is dissipated largely, although not completely, by the production of ionizations, that is, by the knocking out of electrons from atoms. These electrons then in turn may ionize other atoms. And it takes an average of about 32.5 electron-volts to produce one ionization of this kind.

Consequently, an X or gamma ray may ionize many atoms along its path. The ionization of the atoms in turn produces physical and chemical changes in the molecules with which those atoms are associated; for example, causing the breakage of chemical bonds and other structural alterations.

These physical and chemical changes in turn lead to the production of biological changes which usually appear at a somewhat later time. The chemical and physical changes are almost instantaneous, but the biologicl changes may not appear for an hour or two, or sometimes days or weeks after the radiation.

The nature of the damage with which we are concerned falls into several categories. Of major concern is the damage which occurs in DNA, and it is well doumented that even a small structural change in a single gene may initiate a major disease process. This is not an inevitable consequence: The mutation that may be produced may be inconsequential. And it should be pointed out that repair by the body is a very efficient process.

Radiation may also cause chromosome breaks in which affect the genetic material. Each chromosome contains many genes, and a structural defect such as a break in a chromosome may involve then the loss of large amounts of genetic material, which would disappear from the cell during subsequent divisions. This could cause major abnormalities in that cell or cell death. In a multicellular organism we are not really very much concerned with cell death because an organism with many cells can do without some. There are usually other cells that can conduct the same function. So this is not a great problem.

What is a problem is when one deals with a cell that has been genetically altered but does not die: It survives, divides, and gives rise to a host of other abnormal cells which subsequently are responsible for the initiation of a disease process such as cancer or leukemia.

The production of mutation in reproductive cells is of particular concern because defects occurring in those cells can be transmitted to future generations.

The human systems that are most sensitive to ionizing radiation are the bone marrow, the lymphoid tissue, and the reproductive cells. And for this reason heritable defects and leukemia can be induced by very low radiation doses. For example, it has been reported that 1 to 2 roentgens of X-ray exposure in utero causes a significant increase in the leukemia incidence.

The fetus is much more sensitive to radiation than the adult, especially with respect to the brain tissue. The key here is that in the fetus the cell systems are rapidly dividing, and rapidly differentiating, and it is during those stages of early development that radiation has the most marked effects.

As a consequence of this, abnormalities of the central nervous system, such as mental retardation of various types or brain cancers, are common findings in individuals who have been irradiated in utero.

The majority of human data are derived from studies of individuals who were medically or occupationally exposed to radiation, and from the populations of Hiroshima, Nagasaki, and the Marshall Islands. A summary of the effects again is given in the written testimony. I will mention them only briefly.

Radiation, of course, is capable of killing. The lethal dose for humans who are untreated, who are exposed to acute whole-body radiation, is approximately 450 roentgens. Other damaging effects of radiation are blood disorders, different types of cancers, cataracts, decreases in fertility, growth retardation in individuals who are irradiated in utero, congenital defects, life-shortening after chronic exposure to low doses of X-rays and other ionizing radiation, and changes in the immune responses of the body.

Thresholds for specific types of radiation damage have unfortunately not been established for humans. The practical approach that has been used is to determine the least dose that is required to produce a statistically significant effect.

When one is dealing with very low doses of exposure, particularly over long periods of time, it really takes an enormous population to find statistical deviations from the norm. And it becomes very difficult to make assays of thresholds at low doses. This is complicated by the fact that the damage produced by radiation is not unique. It can be simulated by spontaneous events, drugs and other chemicals. Therefore, even when one sees such a change in an irradiated population, it is often very difficult to correlate cause with effect.

It is also somewhat risky to extrapolate animal data. It is quite true that the general types of radiation damage that one sees in mammals used for experimental purposes closely parallel those found in humans. But quantitatively there may be big differences. For example, there is no law that says that a particular dose of radiation that gives a particular magnitude of a specific effect in an irradiated animal will produce the same magnitude of effect in the human. The current safety standards for radiation exposure which are cited in the written testimony are set somewhat arbitrarily at levels below those shown to be damaging statistically.

In point of fact, it should be noted that a single ionization in the appropriate place can, potentially at least, produce a detrimental mutation.

Insofar as nonionizing radiation is concerned, I would like to concentrate on microwaves, again because of their increasingly widespread use, as has already been mentioned by the chairman.

Most of the effects caused by nonionizing radiation are thermal effects, that is, they cause an increase in body temperature. Many of the effects are reversible, that is, they are not permanent changes.

Characterized, nonionizing radiation has very low energy associated with it, usually a fraction of one electron volt. That's the reason they are not able to produce ionizations. There is not enough energy available.

In the case of microwaves, one usually describes them in terms of their frequency, which is inversely related to the wave length. The unit of frequency is the megahertz, which is the equivalent of 10 to the 6th cycles per second.

Most biological work is done at frequencies of 2,000 to 3,000 megahertz because these are the frequencies that are used in many microwave generating instruments.

The microwave power emitted, or the energy absorbed is given in watts or milliwatts per centimeters square; the amount of energy absorbed depends to a large extent on the electrical properties of the tissue. In general, tissues that have a high water content will absorb relatively greater amounts of microwave energy. The greater the frequency, the less deeply the microwaves penetrate: at frequencies of 10.000 megahertz or higher, microwaves do not penetrate beyond the skin. On the other hand, at frequencies below 150 megahertz they pass through the body with very little energy loss. In other words, there is very little interaction with tissue at mircrowaves of that frequency or lower.

The mode of action for microwaves is somewhat controversial at the present time. There is general agreement that at power density of 100 milliwatts per centimeter square or greater microwaves produce thermal effects, leading to hyperthermia and death. In the 10 to 100 milliwatt per centimeter square range, microwaves are presumed to cause thermal damage, but there is some question in the minds of some experimenters as to whether or not the findings are totally related to heat effects.

There is a feeling in some quarters that hot spots may be produced. The term refers to some localized area of the tissue that is heated to a greater extent than the surrounding tissues. As a result, even if the microwave heat measuring instruments don't register increased temperatures, there may be localized damage in such hot spots.

A number of effects have been reported to occur at power densities of 10 milliwatts per centimeter square or lower. A satisfactory explanation as to how such effects might be produced is lacking at the present time. There are some theories, but none are substantiated experimentally.

Insofar as the biological effect are concerned, most of the data come from experimental studies with a variety of mammals. Human data are derived from accidential exposures to microwave-generating equipment and from retrospective studies of occupationally exposed personnel.

Some examples of the effects produced are the following: First and foremost I cite the production of lens opacities and cataracts, because this is the only human disease that is documented as being definitely produced by microwaves.

I have included in the written testimony a chart showing some of the experimental data pertaining to lens opacities and cataracts as they are produced in rabbits, to give you a feeling for the types of experiments that have been conducted and to show some of the great variety of experimental parameters that are involved.

Human cataracts have been documented: Over 60 cases have been reported in the literature by Dr. Zaret. For most of these, however, it is very difficult to determine the dosage or duration of exposure.

These are transient changes. Human lymphocytes have been observed to revert to immature forms in vitro after exposure to a few microwatts per centimeter square. This information has not yet been published, and could therefore not be verified by me. Again, this is a transient reversible phenomenon. The same has been demonstrated in mice in vivo.

A host of behavioral changes have been produced by chronic exposure to low-power densities such as 1 milliwatt per centimeter square, according to some Soviet and Eastern data. This has been found in both animals and humans.

Recently, Dr. Albert reported a change in the exchange of materials between the blood and the brain tissue. Furthermore, evidence indicates that microwave effects may be cumulative. Whereas a single exposure to a particular power density of microwaves does not produce a sizable effect, repeated exposure at that same power density do so. This has been well documented and reported by Dr. Carpenter, as well as others.

Again, it's very difficult to determine thresholds for microwave effects because of the large number of experimental variables involved and because of the low energy involved.

The extrapolations of data from experimental animals to humans is very risky because the exposure conditions are so extremely different. Laboratory experiments are performed under rigorously controlled conditions: The animal is usually held immobilized, and exposure is usually limited to one body part. When we talk about human exposure, in many cases the individual is not even aware of the fact that he is being exposed. Therefore it is very difficult in retrospect to determine the type and amount of exposure. Furthermore, the irradiation, except for the few acute cases reported, is usually of the chronic variety, extending over long periods of time, involves the entire body, and of course the subject's movements in the radiation field are unrestricted.

The present standard was derived from studies which indicated that 100 milliwatts per centimeters square was the lowest power density which could produce damage. So a safety factor of 10 was built in.

Many investigators, such as Seth and Michaelson, feel that this standard is adequate, whereas others are quite dubious about this same standard.

I would like to conclude merely by pointing out two possible problems with the current microwave standards. They are the following: First, there is at present no time limit set on the exposure, and consequently the standard tends to ignore possible cumulative effects. Second, there are, as I have pointed out, some indications that effects may be produced at power densities below the 10 milliwatt per centimeter square safety standard. I hasten to add that "effects" do not necessarily represent "hazards."

Thank you.

Senator FORD. Thank you very much, Doctor.

When it was announced that we would have these hearings and I would be chairing today, I received several phone calls asking me if I would ask these questions. They are very sensitive questions. I ask these questions because my constituents have expressed concerns.

Several years ago, and in fact, I had three calls that related to this—several years ago, X-rays were used to, in laymen's words, to dry up tonsils. And it was 20 years later that there appeared that X-ray treatment may have created cancer. Is that a possibility?

Dr. SCHIFF. Yes, sir. It is. There are several groups studying this. I think the largest one is associated with the University of Chicago. Their data seem to indicate that there is a great increase in the incidence of thyroid cancer in individuals who were exposed in adolescence to radiation for the purpose of treating enlarged tonsils and acne.

Senator FORD. Is there a time frame in which this problem would develop? Could you say that after *x* number of years, if nothing developed, in all probability it will not?

Dr. SCHIFF. I think the peak incidence has been reported to occur 10 to 15 years after the irradiation, after that it drops off dramatically; after 20 years I think it becomes insignificant.

Senator FORD. All right.

The other request was associated with thyroid. And the constituent said that under controlled conditions the patient receives a certain dosage of X-radiation. I understand that then the patient would have to be out of contact for a couple of days and then not expose himself to small children or those with pacemakers. I hope you understand what I'm saying without using technical terms.

Dr. SCHIFF. Yes; in this case you're talking about a radioactive isotope that is given internally. And what has been used in the past for thyroid scans to determine if there is damage, or to treat cancer of the thyroid or other conditions is massive doses of iodine-containing isotopes that will localize in the thyroid. Some of that does spill over to other body tissues and does represent a hazard, particularly if it's given to women who are pregnant. And the material is excreted over a period of a few days.

Senator FORD. So the doctor can keep surveillance over that patient.

Dr. SCHIFF. You could keep surveillance. But you cannot hasten the excretion of the material. So there is some danger. But there are now substitutes that are far less damaging.

Senator FORD. Where do you see the greatest gaps in our knowledge of health effects, or the greatest need for the resolution of current issues?

Dr. SCHIFF. Well, that's hard for me to pinpoint. On the microwave front I'm somewhat concerned over the voluminous reports in the Soviet literature which indicate that there are all sorts of effects at very low exposure doses to microwaves.

I think we have a tendency sometimes to pooh-pooh these data because the Soviets are not as meticulous about reporting the experimental conditions. But I feel that possibly some attempts should be made at least to duplicate some of these experiments to see if they are reproducible. On the ionizing radiation front, I guess my greatest concern would be with the overusage of medical X-ray for either diagnosis or for therapy. There have been changes in usage, but the overall amount of radiation that is being given for clinical reasons is on the increase.

Senator FORD. What do you believe deserves the priority attention for the research community?

Dr. SCHIFF. I would say the medical diagnostic and clinical exposures are of concern.

Senator FORD. Do you think that the American public is safe from exposures to unnecessary radiation?

Dr. SCHIFF. I wouldn't go so far as to say 100 percent safe. But I think we are concerned here, to use a trite phrase, with benefit-risk ratios. In other words, there is always a conceivable possibility that a diagnostic X-ray can initiate a severe disease process. But the chance of that occurring is so slight that it would be foolish to cut out that type of diagnostic procedure, which would be of great benefit to a patient, just because there is a potential risk that some radiation damage may occur.

Senator FORD. Doctor, I thank you for your very informative and detailed testimony this morning. We're delighted you could come today.

[The statement follows:]

STATEMENT OF DR. STEFEN O. SCHIFF

THE GENERAL CHARACTERISTICS AND BIOLOGICAL EFFECTS OF IONIZING AND NONIONIZING RADIATION

I. The electromagnetic spectrum

The types of radiation which represent potential human hazards cover most of the electromagnetic spectrum, which is shown schematically on the next page. The wavelengths of the various types of radiation are given in the left-hand column in angstrom units (1 angstrom$=10^{-8}$ cm). On the right, the energy associated with the radiation is given in electron volts (eV). It may be seen that as the wavelength decreases, the energy increases. Radiations with short wavelengths and high energy such as X-rays and gamma rays, shown at the top of the chart, are capable of ionizing atoms. Those with longer wavelengths and less energy, such as ultraviolet, infra-red, microwaves and radar, do not possess enough energy to produce ionizations.

Not shown in the chart are various types of particulate radiation (that is, radiation consisting of particles that have mass), such as betas, positrons, protons, neutrons and alphas. These are products of natural decay chains, and may also be produced by artificial means. Their energies and wavelengths differ according to their source, but all fall into the "ionizing radiation" category.

II. Ionizing radiation

I will concentrate on non-particulate (i.e. lacking mass) radiation, namely X and Gamma Rays, because these are used clinically and therefore constitute a major source of human exposure. They consist of photons (packets) or continuous waves of energy travelling at approximately the speed of light. Because of their high energy and short wavelength, they have great penetrating power: the greater their energy, the deeper they are able to penetrate tissue.

The unit of Gamma or X-ray exposure dose is the Roentgen (R). Although various definitions exist, in practidal terms 1 R provides enough energy to produce 2×10^{12} ionizations per cc or gram of tissue. The unit of absorbed dose is the Rad. The energy associated with 1 Rad is just slightly higher than the energy dissipated by 1 R.

The sequence of events initiated by ionizing radiation is as follows. The energy of the radiation is dissipated by the production of ionization, that is, by knocking electrons out of atoms. These electrons in turn may ionize other atoms; approximately 32.5 electron volts of energy are required to produce one ionization. One X or Gamma ray therefore may ionize many atoms in its path through tissue. As the energy of the radiation is dissipated, the number of ionizations per unit of path increases, so that the greatest concentration of ionizations occurs at the end of the path. The ionization of atoms, in turn, produces physical and chemical changes, such as bond breakage in molecules and other structural alterations. These physical and chemical changes subsequently lead to the production of biological effects.

It is not possible to cover all of the various effects produced by ionizing radiation within this limited time span. I shall therefore concentrate on the types of damage which are of major concern to humans. The molecule which must be singled out as having the most impact is DNA (deoxyribonucleic acid), the genetic material, which is very susceptible to radiation damage. Even a small alteration in a single gene may result in the production of a mutation. Such a mutation may be inconsequential; on the other hand, it may lead to the production of major abnormalities, such as malignancies. A host of human diseases which are traceable to mutations have been identified in recent years. All of these can be induced by radiation, although they may also be the result of spontaneous errors or chemical effects. For example, the disease Phenylketonuria is due to a very miniscule gene defect, which leads to the production of an abnormal substance within the body (phenylpyruvic acid).

As you are aware, genes are packaged in large groups within cellular structures called chromosomes. Radiation has the capability of breaking chromosomes, an effect which often results in a loss of many genes. Such a loss would lead to major cell abnormalities or even cellular death. It should be pointed out that such cell death is usually unimportant to a many-celled organism because hundreds or thousands or perhaps even millions of other cells exist which can assume the same function. However, a genetically altered cell that survives may give rise to other abnormal cells. For example, if an abnormal bone marrow cell is produced, this single cell may continue to divide and give rise to more cells of the same type; it is via such a mechanism that leukemia may be induced.

Mutations of the reproductive cells are of major concern because such damage may be transmitted to future generations. In humans and other mammals, the systems that are most sensitive to radiation are bone marrow, lymphoid tissue, and the reproductive cells of the testes and ovaries. For this reason, heritable effects and leukemia can be induced by very low radiation doses (increased leukemia incidences have been reported following *in vitro* exposures of 1–2 R).

The fetus is much more sensitive to radiation than the adult. This is especially true with respect to developing brain tissue. Abnormalities of the central nervous system, including microcephaly, mental retardation and brain cancer, are consequently among the more common findings in individuals irradiated *in utero*.

The majority of human data is derived from studies of individuals who were exposed medically or occupationally, and from the irradiated populations of Hiroshima, Nagasaki and the Marshall Islands. A summary of the effects known to be caused by radiation include (1) lethality: the dose of acute, whole-body radiation required to kill 50 percent of the individuals is approximately 450 R; (2) blood disorder, especially leukemia, multiple myeloma and palastic anemia; (3) carcinomas, especially of the thyroid gland; (4) cataracts; (5) decreases in fertility; (6) diminished immune responses; (7) growth retardation in individuals irradiated *in utero;* (8) congential defects in individuals irradiated *in utero;* (9) life shortening after chronic exposure.

Regarding thresholds to radiation damage, it may be stated that no true threshold has been established to date. Threshold doses discussed in the literature usually refer to the least dose of radiation that will produce a statistically significant effect. If the exposure involves very low doses, especially when these are distributed over a long period of time, it becomes virtually impossible to detect a radiation effect unless an enormously large population is being examined. As previously indicated, the damage produced by radiation is not unique: the same effects can occur spontaneously or be induced by various chemicals. Therefore, event if an effect is seen, it may not be possible to limit it to a single specific cause.

Although the radiation responses of several types of mammals are similar to those of humans, an extrapolation of experimental animal data to humans is fraught with uncertainty. This is especially true where the quantity of radiation necessary to produce a given effect is concerned. For example, the general types of radiation damage seen in mice irradiated *in utero* are similar to those seen in humans, but the specific dose required to produce the same incidence of the same defect may be vastly different.

The present radiation safety standards, namely, 0.1 rem (Roentgen equivalent mammal) per week or 5 rem per year for occupational, and 0.17 rem per year for non-occupational exposure, are set arbitrarily at levels below those shown to be damaging statistically. In point of fact, a single ionization in the right place can potentially produce a detrimental mutation.

III. Non-Ionizing radiation

This discussion will focus primarily on microwaves because of the increasingly common usage of microwave generating instruments.

The characteristics of microwaves and other non-ionizing radiation differ greatly from those of ionizing radiation. Microwaves have a very low energy (a fraction of one eV) and therefore cannot produce ionizations. They are usually described in terms of their frequency, which is inversely related to the wavelength. The unit of frequency is the megahertz (Mhz; equivalent to 10^6 cycles per second). Most biological work is done at frequencies of 2,000 to 3,000 Mhz, because these frequencies are currently used in many microwave generating instruments.

The microwave energy absorbed is given in Watts (W) or Milliwatts (mW) per cm^2. Exposure, either accidental or experimental, ranges from power densities of more than 1 watt/cm^2 to less than 1 mW/cm^2.

The amount of microwave energy absorbed depends upon the electrical properties of the tissues (dielectric constants and conductivity); in general, tissues with high water content will absorb relatively greater amount of microwave energy. The greater the frequency of the microwaves, the less deeply they penetrate: at 10^3 Mhz and higher frequencies, they do not penetrate beyond the skin; at frequencies below 150 Mhz they pass through the body with very little interaction.

The means whereby microwaves produce damage is somewhat controversial at present. Microwaves of power densities of 100 mW/cm^2 or greater are generally conceded to produce thermal effects, with prolonged exposure leading to hyperthermia and death. Microwaves in the 10 to 100 mW/cm^2 range are generally presumed to cause thermal damage, but there is some question as to whether or not the effects are entirely due to heating. Some researchers feel that differential heating of tissue may lead to the production of "hot spots", that is, small areas which absorb more heat than the surrounding tissues, so that localized thermal damage would occur. A number of effects have been reported at power densities of 10 mW/cm^2 or lower, but a satisfactory mechanism to explain how the damage might be produced at such levels has not yet been determined. A variety of physical and chemical changes have been proposed, but supportive evidence is lacking.

Most of the data pertaining to the biological effects of microwave come from experimental studies involving rabbits, mice, dogs and other mammals. Human data are derived primarily from acute accidental exposures to microwave-generating equipment, and from retrospective studies of occupationally employed personnel.

A variety of biological microwave effects have been documented. Whereas most of the earlier work was limited to a study of thermal effects produced with higher power densities, more recently attention has been given to lower exposure doses and the effects of long term irradiation.

The organ studies in the greatest detail is the eye, because it was discovered a number of years ago that microwave could induce lens opacities and cataracts in mammals. It is well documents by R. L. Carpenter and others that lens opacities may be induced in rabbits after exposure to 100 mW/cm^2 or more of microwaves. A summarizing graph (next page) is provided to illustrate the data available and the numerous experimental parameters involved. Human lens opacities have also been reported: over 60 cases have been cited in the literature by Dr. M. Zaret, most of which were due to accidental exposures to microwave generating equipment. One of the more disquieting findings, demonstrated rather conclusively by Dr. Carpetner, is that the effects of microwaves may be cumulative: whereas a single exposure does not produce a visible effect, repeated exposures at the same power densities do.

Other effects that have been attributed to microwave include the following:

1. destruction of reproductive cells in mice has been reported with exposures as low as 10 mW/cm^2.
2. temporary changes in protein synthesis have been observed in experimental animals;
3. lymphocytes of humans have been observed to revert to immature forms (—blasts) in vitro after exposures to a few microwatts/cm^2;[1] the same effect has been found in mice in vivo.
4. the ability of some humans to "hear" microwaves has been well documented;
5. recently, modifications in the exchange of molecules between the blood and brain tissue were reported by Albert.
6. a host of central nervous system and behavioral changes have been reportedly produced in humans and experimental animals by chronic exposure to very low power densities such as 1 mW/cm^2, according to Soviet data.

As was the case with ionizing radiation, it is exceedingly difficult to determine thresholds for microwave damage, not only because of the low energy involved, but also because of the large number of experimental variables. Extrapolations of data from experimental animals to humans are very risky because the conditions of exposure vary greatly from one to the other: most laboratory experiments are performed under rigorously controlled conditions, with the animal immobilized, and with exposure usually limited to one body part; however. human exposure often occurs without the individual's knowledge, usually involves the chronic irradiation of the entire body, and does not entail a restriction of the subject's movements within the radiation field.

The present safety standard of 10 mW/cm^2 was derived from studies which indicated that 100 mWcm^2 was the lowest power density at which biological effects could be demonstrated. It was felt that a safety factor of 10 would be sufficient. There is some controversy as to the adequacy of the present standard, particularly in view of the fact that the Soviet safety standard is considerably lower. A number of American researchers, such as Seth and Michaelson, feel that the 10 mW/cm^2 standard affords adequate protection. Others, such as Tengroth et al and many of the Russian and Polish researchers, have a contrary view. Based on a survey of current literature, I feel that two points should be considered with regard to the present standards. The first is that the present standard sets no time limit on the exposure, and therefore ignores possible cumulative effects which may accrue over a period of time. The second is that the present standard tends to ignore the data which suggest that effects may be produced at power densities below 10 mW/cm^2.

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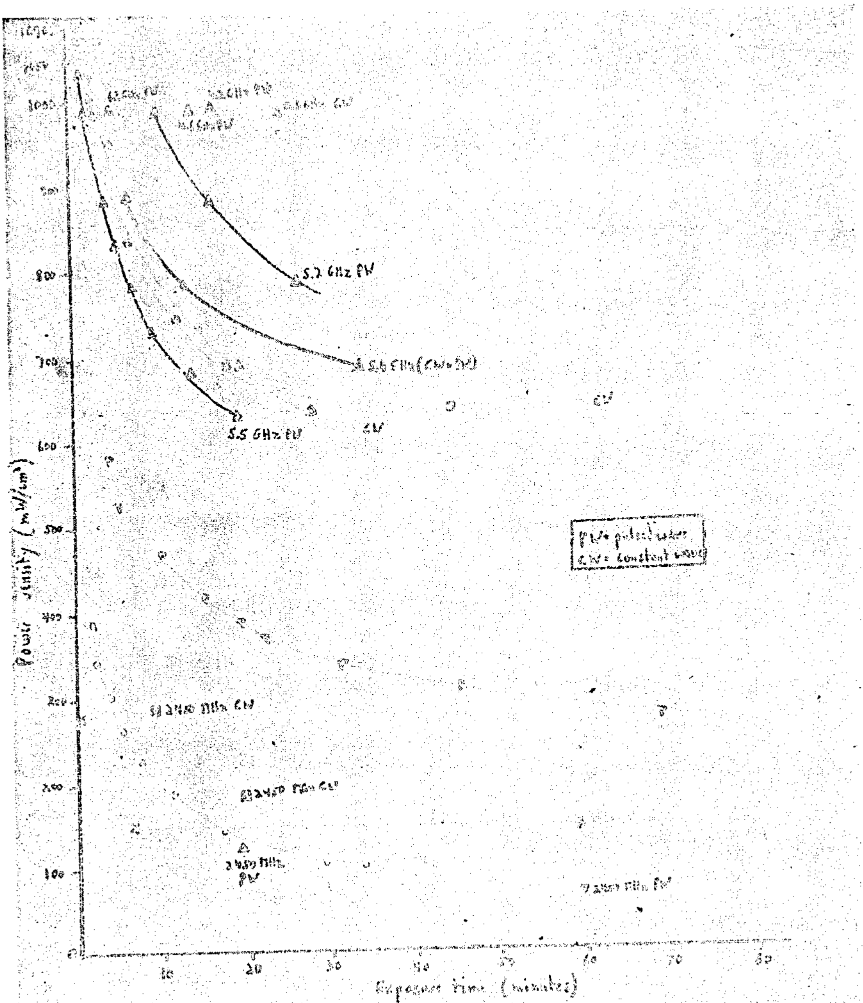
[1] An unpublished personal communication and therefore not verifiable by author.



THRESHOLDS FOR LENS OPACITIES IN RABBITS AFTER SINGLE EXPOSURES TO MICROWAVES

Carpenter & van Ummersen (1968); Carpenter (1962); Carpenter (1958); Carpenter (1958); Williams et al (1955); Birenbaum et al (1969); Kramer et al (1975); Ely & Goldman (1957)

Senator Ford. The next witness will be Mr. Sherwin Gardner, who is the Deputy Commissioner of the Food and Drug Administration, Department of Health, Education, and Welfare. He is accompanied by Mr. Richard Merrill, General Counsel and John C. Villforth, Director of the Bureau of Radiological Health.

Doctor, given the fact that the committee received copies of your testimony and written answers to our questions only yesterday, we have had inadequate time to review this material. I want to note that the committee may submit further questions to FDA at a later time, and we may invite you back for further testimony.

STATEMENT OF SHERWIN GARDNER, DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY RICHARD MERRILL, GENERAL COUNSEL; AND JOHN VILLFORTH, DIRECTOR, BUREAU OF RADIOLOGICAL HEALTH

Mr. GARDNER. Yes, Senator. That would be fine. We are perfectly anxious and willing to help.

Senator FORD. I wanted to make that part of the record so we understand each other.

Mr. GARDNER. Yes, sir.

Senator FORD. Doctor, you may proceed. You may submit your prepared statement for the written record and highlight it orally if you wish.

Mr. GARDNER. Perhaps if it is acceptable to you, I will go through the statement. I have made some editorial changes in it for ease of presentation. But there are no substitutes.

Senator FORD. That will be fine.

Mr. GARDNER. Thank you, Senator.

We do welcome this opportunity to discuss with your committee the FDA's activities to protect public health through enforcement of the Radiation Control for Health and Safety Act of 1968.

The FDA is responsible, with other agencies, for the reduction of unnecessary human exposure to manmade radiation. To accomplish this goal, our Bureau of Radiological Health engages in a variety of activities to reduce public exposure to known radiation hazards. These activities can be categorized by three major areas:

Regulation—issuance of performance standards and programs to insure compliance;

Research—to obtain knowledge necessary to develop standards and use control programs; and

Education—to inform users how to use products safely.

The statutory base for these programs is Public Law 90-602. In fiscal year 1977 approximately $19,100,000 is being expended for consumer protection in radiological health.

Since we are responding to a series of questions from the committee which describe many of our activities in detail, my statement today only highlights some of the more significant accomplishments and activities of the agency's program on radiological health. I will briefly discuss how FDA interacts with State agencies and organizations in furthering our mutual goal of reducing unnecessary exposure to radiation in this country.

Our statement includes a brief discussion of how the FDA interacts with various agencies in furthering our goal of reducing unnecessary exposure to radiation in this country. There are three parameters we have developed to carry out our objective of promoting radiation health and safety.

The first program area concerns ionizing radiation, and included in that are products such as X-ray equipment. The second program area is devoted to light and sonic radiation and lasers and mercury vapor lamps are examples of such products. The third area is radiofrequency radiation, which would include microwave ovens.

Each of these program areas are grouped into several functional components: Biological research; general research—including equipment and the development of measurement instruments and techniques to determine equipment performance; the related triad of performance standards, compliance, and surveillance; the development and issuance of guidelines for use, education, and training; and Federal/State relations.

This program concerns itself with development of performance standards for products, devices, as well as use control. To give you some indication of what is involved in this one area alone, there are approximately 13 million television receivers manufactured each year. Every TV set manufactured since June 1971 has had to be certified by the manufacturer—domestic and foreign—as being in compliance with FDA's performance standard. With about 100 million sets in the United States, a large segment of American households look to the FDA for daily protection in that area alone.

Medical and dental diagnostic X-ray systems also fall into the ionizing radiation category. Approximately 160 million persons will receive one or more X-ray examinations in 1977. Some 15,000 new diagnostic X-ray systems are installed annually. In dollar value, a new diagnostic X-ray unit can cost from several thousand dollars up to three-quarters of a million dollars for CT body-scanning systems. Since this performance standard went into effect on August 1, 1974, each X-ray unit has to be certified as meeting the standard.

Components covered by the standard are tube-housing assemblies, X-ray controls, X-ray high-voltage generators, fluoroscopic-imaging assemblies, tables, cradles, film changers, cassette holders, and beam-limiting devices. The last item, beam-limiting devices, is one of the most important provisions of the standard. It is aimed at a major cause of unnecessary X-ray exposure—the practice of using an X-ray beam larger than needed to produce a diagnostically acceptable radiograph.

Light—as in lasers—and sound—as in diagnostic devices used to detect the positioning of the fetus—are examples of modern radiation technologies being applied to everyday experiences of the American population. Increasing numbers of supermarkets are using laser systems for checking out purchases and maintaining a constant inventory. In the field of sonics, it is estimated that about one-third of all newborn babies are being subjected to sonography, contrasted to 10 years ago when only a small percentage was exposed.

On the basis of the past few years, we can expect that the use of light and sonics products will continue to expand, with concomitant increasing requirements upon the FDA for effective control over such devices to eliminate unneeded exposure and to insure to the Nation that the devices are safe to use.

The FDA's activity in this field takes us into virtually every American's kitchen and dining room. From a relatively low level of 55,000 units being sold annually at the time of the promulgation of our microwave oven standard in October 1971, the microwave oven industry today is producing approximately 1.5 million ovens a year. And we understand the sales figures are still climbing.

The same certification requirements apply to manufacturers of microwave ovens as apply to makers of television receivers, diagnostic

X-ray systems, and other radiation producing electronic products. Each oven must bear a permanent label which states that it is in conformance with the applicable FDA standard.

For the record, I would like to submit a document titled "A Look at FDA's Program To Protect the American Consumer From Radiation." [1] It spells out in some detail what FDA has been able to achieve in a relatively few short years. I will only touch in summary form on some of the more significant achievements set out in this document:

It is estimated that approximately 270 million X-ray examinations will be performed in 1977. For the X-ray units sold in 1976, alone, the savings in future health care costs as a result of lower radiation exposure required by the applicable standard is estimated to be in excess of $70 million a year, primarly resulting from the provision in the X-ray standard concerned with the limitations of the X-ray beam to size of the X-ray film, thereby eliminating unproductive radiation exposure which would increase the potential health hazard.

Other products that are widely used by Americans and which are subject to FDA regulations are television receivers and microwave ovens. Virtually every home has a TV set while there will be 11 million ovens in use in homes by 1980. A survey of the former product type conducted in late 1967 revealed that 6 percent of the over 11,000 receivers tested were emitting radiation in excess of the industry's own standards. Other studies observed a potential maximum exposure rate of 800 roentgens per hour.

These findings were presented during the 1967–68 hearings before this committee, which led to the passage of the Radiation Control for Health and Safety Act of 1968. The FDA standard, effective on January 15, 1970, applies to all television receivers manufactured subsequent to that date and limited the amount of radiation that can be emitted from a set to 0.5 milliroentgen per hour at a distance of 5 centimeters—or 2 inches—from any point on the surface of the set. Continual in-house evaluation of the radiation emission levels from TV receivers show that current emissions are essentially unmeasurable. Therefore, as a result of the FDA standard, industry has designed and manufactured these products so that the public can use them without fear of injury from leakage radiation.

FDA's continuing evaluation of consumer products also includes microwave ovens. The impetus behind the development of a performance standard for microwave ovens resulted from a 1970 combined Federal/State industry survey, performed on 4,033 ovens—produced by 17 manufacturers—which revealed that approximately 20 percent of the ovens emitted leakage radiation in excess of 10 milliwatt per centimeter to the second power. The FDA standard, effective October 6, 1971, imposed a more stringent emission level limit: 1 milliwatt per centimeter to the second power at the time of purchase, and 5 milliwatt per centimeter to the second power for the life of the product.

Some 200 million passengers travel by airplanes each year. The use of X-ray systems for security or surveillance purposes to protect those Americans evolved from the introduction of X-ray equipment which met the FDA standard into airports for screening hand-carried luggage. There are an estimated 477 such X-ray detection units in use at one-third of the Nation's airports. Our regulation assures that the operators of the units and the public will not be exposed to unnecessary radiation.

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[1] Available from the Agency, HEW publication FDA 77–8032.

These and many more examples of the effects of FDA's radiation control program will be found in the compilation of FDA efforts to protect the American consumer which I have previously offered for the record to the committee.

There is another important document which has been submitted to the committee, which I would like to mention at this point. It is the "Highlights of Major FDA Radiation Protection Activities." The document identifies more than 470 FDA efforts in effecting and carrying out an electronic product radiation control program. About 60 percent of the listed activities involve either biological effects research or general research into such activities as measurements and instrumentation.

The biological effects projects constitute slightly under one-half of all research activities. The other 40 percent of the highlighted activities are related to such other areas of program concern as compliance, surveillance, and performance standards development; education and training activities; and Federal/State relations.

FDA's cooperative relations with the State radiological health programs occupy a very important place in the control of unnecessary X-ray exposure to Americans. In the field of diagnostic X-ray systems, the FDA has contracts with 18 States to assure the compliance of newly installed diagnostic equipment. The cost of this program is about $310,000 a year.

A combined Federal/State task force developed a system known by the acronym NEXT (Nationwide Evaluation of X-Ray Trends) which measures the effectiveness of State and Federal regulatory activities to reduce patient radiation exposure. The system, adopted by 39 States and seven Federal agencies, relies on a standardized onsite survey of commonly employed diagnostic X-ray procedures so that the magnitude of exposure for a particular facility can be compared to the "national" exposure throughout the country. This system allows State radiological health surveyors to point out to physicians and dentists exposures that are excessive and recommend appropriate corrective actions.

Earlier, I discussed the effect of standards in reducing unnecessary radiation exposure. There is another side to the protection coin—user control. One could go on at great length describing the scope and content of FDA's programs in the use area. While time does not permit me to go into detail, let me outline some major ongoing FDA programs.

FDA has developed voluntary medical radiation recommendations designed to provide health care practitioners and ancillary personnel with guidance about various issues affecting the radiation exposure of patients. These recommendations are published in the Federal Register and backed by dissemination of relevant materials to the health professions. Recommendations under development include X-rays during pregnancy, use of routine chest examinations, quality assurance for X-ray facilities, and other suggestions. We have published in the Federal Register a notice of intent to develop recommendations on use of X-rays during pregnancy and for quality assurance for X-ray facilities.

X-ray technologists now have the opportunity to upgrade their capabilities through use of an FDA developed syllabus on radiation protection, as well as the use of an FDA designed and produced multimedia training packaged series. Approximately 1,500 of the training programs are now in use. An estimated 10,000 to 12,000 technologists will view this material each year. It should reach some 20,000 of the estimated 75,000 credentialed X-ray machine operations each year.

FDA has also developed a Radiological Health Sciences Learning Laboratory for use by medical school students, radiology residents, and practitioners. This system was designed to reach all three elements of X-ray usage: Patient selection, conduct of examination, and interpretation of the results. The laboratory is presently in use in 49 medical schools, with an additional 26 scheduled for use. We anticipate that by 1980, all U.S. medical schools will have integrated this system into their overall medical education program.

Another use control program involves dentists, State radiological health programs, and the FDA. It is known as DENT, the Dental Exposure Normalization Technique. Based upon data secured through use of a simple radiation measuring device, dental facilities with abnormally high patient exposures are identified and visited. Corrective actions are suggested.

At present, the DENT program is being used to monitor about 75,000 dental X-ray machines, constituting about two-thirds of those in the United States. States report an average 40-percent reduction in patient exposure to X-radiation.

These represent but a few efforts which the Agency has initiated in the use-control area. We would like to submit for the record a recently developed document which more thoroughly summarizes FDA's educational programs and overall use-control activities.[2]

In two medical radiation fields of particular current interest, FDA has again become involved because of its concern for reduction of patient exposure. One area is the use of computed tomography (CT). Another is mammography. The FDA has been concerned with assuring that a diagnostic device such as the CT scanner (which is the subject to the FDA X-ray standard) does not unnecessarily expose patients in the process of utilizing a new diagnostic technique.

The Agency has a similar concern for mammography. Considering the usefulness which is attributed to this cancer-detecting technique, we want to be able to assure women patients that what is gained through saved lives by use of this early cancer detection system, will not be offset by a level of X-ray exposure that could contribute to the development of breast cancer.

Throughout the FDA, there is recognition of the need for science as a basis for regulation. The BRH, through its highly focused research competence, has been able to develop scientific information, to evaluate research data from others, and to offer significant scientifically based advice to other organizations.

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[2] See a "Summary of Medical Radiation Protection Programs of the Bureau of Radiological Health, Food and Drug Administration," *infra.*

Bureau research programs, therefore, provide direct and indirect support for regulatory standards and guidelines, and impact on programs in other agencies. Research activities are concentrating in the ionizing, microwave, medical ultrasound, and light areas. For example, the Bureau is engaged in research to develop better ways to measure exposure to both ionizing and nonionizing radiations and to determine their biological effects.

Acute exposure to ultrasound has been shown to cause birth defects in rodents and to initiate blood clotting in the region of application. Acute exposure to microwaves of sufficient intensity can cause cataracts; some evidence now points to the possibility of cumulative damage from lower levels of exposure.

The Bureau's analysis of risks from mammography screening played an important role in the decision to restrict use of this technique in women under age 50. Research initiatives into radiofrequency radiation, magnetic fields, airborne ultrasound, and infrared hazards are yet to begin.

Mr. Chairman, there is virtually no aspect of life in these United States that is untouched by any one or combination of the standards developed and administered by FDA—for television receivers, microwave ovens, medical and dental diagnostic X-ray systems, X-ray baggage inspection units, laser products and systems, and cabinet X-ray systems. We are developing performance standards for ultrasound therapy, sunlamps, mercury vapor discharge lamps and microwave therapy. In a preliminary approach, we are looking at X-ray therapy and diagnostic ultrasound systems to determine what are the possible problems connected with their use.

We believe that we are administering a program that is highly innovative and successful in protecting the public health. We are meshing FDA's responsibilities under the Medical Device Amendments of 1976 with our responsibilities under the Radiation Control for Health and Safety Act of 1968. We plan to continue and extend in the future the radiation protection efforts which I have sketched for you.

Mr. Chairman, we will be happy to try to answer any questions you or other members of the committee may wish to ask.

Thank you.

Senator FORD. I thank you, Doctor, for your statement. And I have several questions I would like to ask you.

This committee is trying to determine if, in light of the proliferation of ionizing and nonionizing radiation devices, the American public is safe. Although you state that a number of your programs have lowered the amount of radiation emitted by particular products or equipment, is the public still exposed to more radiation due to the fact that more diagnostic procedures depend on the use of radiation plus the fact that there is more radiation emitting equipment that the public is exposed to? Could you give me your assessment of that question?

Mr. GARDNER. Yes, Senator.

I think that it is a fair statement to say that the risks of exposure to radiation has increased simply because as you pointed out, there are more radiation emitting products. In medical care, there are more diagnostic and therapeutic techniques available today than ever before. Therefore people now have a greater opportunity to be exposed. But balancing that off is the knowledge that this equipment must meet standards which have been designed to assure that any radiation which they receive is safe or, as expressed by the previous witness, there is in the case of medical radiation, a risk-benefit assessment that is made so that the patient can be secure that the benefits he receives from radiation exposure do not exceed the risk that he is exposed to.

As we encounter new technology and new products, we have taken steps to issue standards, that will limit the amount of radiation that people can be exposed to, and establish levels that are considered to be safe.

Now, perhaps Mr. Villforth would like to expand on my answer.

Senator FORD. I am asking you for your opinion, Doctor.

Mr. GARDNER. OK. We will stand on that statement.

Senator FORD. Most observers seem to agree that a large part of unnecessary radiation exposures come from equipment which is improperly maintained and calibrated, and from improper use of either new or old equipment by basically untrained operators.

The FDA answers to this committee's questions indicate that you have established suggested State regulations. The FDA mentioned programs which train 50 to 100 State personnel in proper use techniques. Further, Commissioner Kennedy mentioned that about 8 percent of FDA's inspections are of uncertified or pre-1974 X-ray equipment.

My question is: Are these largely voluntary efforts meeting the need to prevent unnecessary exposure of the public to X-rays?

Mr. VILLFORTH. I am not sure I heard all of the numbers, Senator.

Senator FORD. I said the program would train 50 to 100 State personnel and that about 8 percent of your inspections are of uncertified or pre-1974 X-ray equipment. And what I wanted to know is, are these largely voluntary efforts meeting the need to prevent unnecessary exposure to the public?

Mr. VILLFORTH. The inspections of the FDA are directed at X-ray machines that are manufactured under the X-ray performance standards.

We do not normally inspect old equipment. We encourage the States, who have a specific responsibility under State regulations, to inspect all such machines.

We encourage them and work with them to see that those X-ray machines are brought up to compliance with the suggested regulations of the States.

We do not inspect old X-ray machines. We do not have the right of entry into the physician's office for that purpose. That is the States' responsibility.

Senator FORD. How many States actually inspect the old X-ray machines?

Mr. VILLFORTH. Virtually all of the States, I can't say all, but almost all of the States have some type of X-ray surveillance and inspection program, modeled after the suggested State regulations.

Senator FORD. Well, in your statement, you answer one of our questions: The agency has contracted with the States to obtain data on compliance testing of medical X-ray units.

And you cite 7 contracts let in 1975, and an additional 11 in 1976. And I believe that you say all 18 States are continuing to perform inspections for FDA.

Could you state what the findings of that survey have been and what your plans are for the other 32 States?

Mr. VILLFORTH. The purpose of these contracts with the 18 States—and we hope to have an expanded program to other States in the future—is to help FDA augment its inspection of new equipment.

Senator FORD. New equipment?

Mr. VILLFORTH. Yes; new equipment manufactured under the X-ray performance standard.

So the purpose of what appears to be a rather limited survey, is actually to inspect and to identify a sample of the compliance of new X-ray machines.

If I may, Senator, let me explain a bit about the nature of the X-ray program and where it would differ from inspection programs involving television receivers or microwave ovens. The validity of our compliance programs, which look at microwave ovens and color TV sets as they are produced, is established by factory-based checks of the design and the quality control of such products. Compliance can also be checked by pulling samples from warehouses or by buying samples of such equipment and testing it in our laboratory.

An X-ray machine is an extremely complicated piece of equipment which consists of many components: the X-ray tube, the X-ray table, the voltage supply and so forth. A physician or a hospital that purchases an X-ray machine may purchase different components of the system from different manufacturers.

While we can be assured that those components are properly manufactured and meet our standard by checking them at the factory, we cannot be assured that when they are assembled, they are assembled propertly, without a thorough check.

Now the purpose, therefore, of such a compliance program, is to inspect the assembler who is considered under our statute as a manufacturer. The assembler must certify that he has properly put together the individual components, which may come from different manufacturers.

Now, the States are in perhaps a better position to establish whether such units are assembled properly in the hospital or in the clinic. Therefore, we rely heavily on the State people to augment our compliance program and to check on the assembly of X-ray systems.

That is what we were talking about in terms of the State contracts, to do that sort of work.

Senator FORD. Well, in answer to the committee's questions, you indicated that 30 to 50 percent of the manufacturers or assemblers were not in compliance with your new X-ray standard.

Does this reflect on the agency's ability to enforce its statutory mandate?

Mr. VILLFORTH. Yes. This reflects a concern that we have. That is a concern that was also called to our attention by the Government Accounting Office report that analyzed the state of compliance. The point is that we are not able to assure that 100 percent of the machines, that are assembled, meet the standards.

Senator **Ford**. You are not even getting close to 100 percent if it is 30 to 50.

Mr. **Villforth**. That is correct.

Senator **Ford**. You are not even halfway there.

Mr. **Villforth**. When machines are found to be assembled inadequately, corrections are made on the spot or soon afterwards to bring them into compliance.

As we get data from those situations in the field, we go back to the manufacturers to see if there is any inherent design defects or engineering defects that could be corrected for all X-ray machines in that same group.

Senator **Ford**. What type of a time frame do you have for making it 100 percent?

Mr. **Villforth**. We hope to add a few more States in the coming year, from the 18 to perhaps 4 or 5 more States by reprogramming the existing dollars that we have, so that we can broaden the base.

I am not certain when we will be able to assure that 100 percent of the machines are checked.

Senator **Ford**. What kind of procedures do you have to go through to contract with a State?

Mr. **Villforth**. Senator, it is not the procedural problems that are holding us up. It is a question of competing needs for resources.

Senator **Ford**. You mean you need more bureaucrats?

Mr. **Gardner**. No. In this case we are talking about dollars to pay the States for conducting these inspection activities.

Senator **Ford**. How much do you have to pay a State?

Mr. **Villforth**. These contracts vary from $10,000 to $25,000, per State which is a small amount to do this type of work.

Senator **Ford**. I imagine a poor State like Kentucky could manage that amount of money, to comply. Is that all it takes?

Mr. **Villforth**. The contract per State is equivalent to almost a man-year of effort. It is about that amount of dollars per State; yes.

Senator **Ford**. Fifty times twenty-five; are we talking about $1 million a year, to have all States insuring compliance?

Mr. **Villforth**. It is not a case, sir, of having the States comply. The situation is we want to use this type of program to assure that the assemblers assembled the systems properly.

Let me make another observation here.

If we found a particular assembler—again, an assembler is treated as a manufacturer—who is chronically putting together machines inadequately, we can take action against that assembler to see that all of the machines that he has put together in the past period of time are checked and brought into compliance without necessarily having to inspect each one of those machines.

There is a multiplication effect from this. It is not necessary that 100 percent of all assembled machines be checked. But rather to make sure that those assemblers, who are doing a creditable job in putting the components together to meet the provisions of the standard.

Senator **Ford**. And that takes $25,000 a year to contract with a State to do that for you?

Mr. **Villforth**. Yes. That is about what it has been running.

Senator FORD. That seems like an awfully small amount to only have gotten 18 States to participate over a 2-year period. Is that all you need? One man per year to check, and then you find a chronic manufacturer, that is an individual who assembles the machinery so that it is not in compliance.

If you find that over a period he is assembling equipment wrong, then you can go back and have all of those pieces of equipment examined and problems corrected. That is an interesting statement. Another question.

You are required to make an annual report to Congress suggesting legislative action. The only thing you have recommended is discontinuing the annual report. Do you believe that the users of this equipment should be subjected to Federal regulation, licenses, certification, so forth? What kind of training is needed to become a technician? Why has the agency not recommended legislation in this respect?

Mr. GARDNER. I am sorry.

Senator FORD. What kind of training is needed presently in most of the States to become an X-ray technician?

Mr. VILLFORTH. With the exception of the few States that have licensing requirements, there is no training requirement for becoming an X-ray technologist. That is, an individual could presumably walk in off the street. A physician could presumably use his secretary to operate an X-ray machine.

However, most of the medical institutions, larger, reputable facilities, do employ certified radiologic technologists. Those are individuals who have been certified by the American Registry of Radiologic Technologists.

There is a program, a specific 2-year training program for those individuals.

But there are, we estimate maybe 40,000 to 50,000, operators of X-ray machines, who do not have this type of credentialing or background or certification. We are concerned about these individuals.

Several of the States have developed State licensure programs to require that all individuals in those States who operate medical X-ray equipment meet certain requirements of licensure. And that is generally related to the type of background that one would have if one were a registered X-ray technologist, certified by the American Registry of Radiologic Technologists.

Senator FORD. When you say several of the States—what is several?

Mr. VILLFORTH. I think we are talking about New York, New Jersey, California, Puerto Rico, and Kentucky.

Senator FORD. Thank you very much. I was Governor of Kentucky when we passed that law. So I am familiar with what you are saying. And I can't understand why the other States have not done it.

I don't want to belabor this point, but it seems to me that you are talking about 40,000 to 50,000 untrained, unqualified people, who are operating X-ray machines on an unsuspecting public.

It seems that ought to be one of your primary objectives, to see that the public is protected to the best of your ability to eliminate the untrained people.

You just said that an individual can walk in off the street.

Mr. VILLFORTH. That's correct.

Senator FORD. And the doctor would say, "There it is, X-ray these people." That shakes old Ford a little bit.

It may be that Federal intervention in this area is necessary.

Mr. GARDNER. Senator, I just want to express our agreement with your concern, that training is an essential element to assure safe use of X-ray equipment and prevent overexposure.

Senator FORD. Would you say that again?

Mr. GARDNER. We are in agreement with you. The training of X-ray technicians is essential to prevent overexposure and to assure safe use of X-ray equipment. It is for that reason that we have been fairly active in our own way in providing information to X-ray users and in encouraging States to adopt measures that would provide for the training of X-ray technologists.

We will be taking some additional steps in the next few months by assembling a committee to try and develop some standards for credentialing technicians.

Senator FORD. I understand Senator Randolph will be introducing his bill on Federal licensing very soon.

You have not suggested any legislative action in your annual report, and I guess you have not suggested any legislative action in this area?

Mr. VILLFORTH. In the area of training, that's correct.

Senator FORD. Licensure, certification, anything?

Mr. GARDNER. No, we have not.

Senator FORD. Let me go back to one question. How much effort does it take to sign a contract with a State to look after those who assemble the X-ray machines?

How much effort would it take on your part to sign up the other 32, outside of some money?

Mr. GARDNER. Well, there is no need for legislation. That requires an appropriations bill, sir.

Senator FORD. I bet you could allocate $1 million if you tried hard enough.

Mr. GARDNER. I won't quarrel with that.

Senator FORD. Thank you very much.

Why don't you cut a million and put it into this area?

You described several studies on the effects of microwaves. And conclude that biological effects of microwave exposure show effects at lower levels than earlier supposed. And microwave associated disease is no longer limited to cataracts and other things.

What is the nature of the additional research? When do you expect its completion?

Mr. VILLFORTH. I do not know when we can expect to have the answer on that particular problem.

I think the type of research we are doing is directed at trying to better understand some of the phenomena that has been reported in the Eastern European literature, which concerns some of the behavioral effects and some of the general nonspecific effects of microwave radiation.

There have been suggestions that microwaves interact with the brain and the neurophysiological system. This has been seen by the Russians and we have also observed it, but at much higher exposure levels than the Russians have reported.

To do the type of research at lower levels of exposure requires more time and larger animal experiments than we now have available.

It will take some years, I suspect, before this type of animal research will support anything new in the area.

We have also done epidemiological studies. We are looking at military personnel, specifically retired Navy employees who worked with radar. These studies were to see if there are any deleterious effects in that population.

So far, that study is not far enough along to determine if there are any real effects on those exposed to radar within the Navy environment.

Those studies must be tested and evaluated. I think we are years away from fully understanding whether all of the phenomena reported in the Eastern European literature are, in fact, real.

Let me point out the concern expressed by your initial speaker, that there are measurable biological effects which may not necessarily be deleterious or a risk to the exposed individual. Although there may be effects such as increased body temperature and change of heart rhythm, these may not necessarily result in detriment to the individual. So the relationship of these effects to the risk of the individual must be checked.

Senator FORD. All right. What is your reaction to the previous witness' statement or his concern about the lack of a time limit on the microwave standard?

Mr. VILLFORTH. I guess I did not quite understand what he said.

Senator FORD. He talked about the time of exposure, I believe.

The length of it, the rapidity of it. Repeated exposure.

Mr. VILLFORTH. The whole question of chronic exposure to microwave, as in the case of the worker, must be examined—needs to be looked at, yes.

The question of the level that has been generally accepted—in this country—by many agencies, that is, 10 milliwatts per square centimeter of occupation exposure, must also be looked at.

Senator FORD. How closely do you work with other agencies such as OSHA to insure that product emission standards are correlated with the exposure standards?

Mr. VILLFORTH. Our relationships are more directly through the National Institutes of Occupational Safety and Health (NIOSH) and the Center for Disease Control; both of these Agencies are in the Public Health Service.

NIOSH is more concerned with developing the criteria of risks from all sources of radiation and, therefore, we work more directly with that group.

For example, we have had exchange visits to their facilities in Cincinnati where they are doing research on the effect, or starting to do research on the effect of radio frequency radiation on the potentially pregnant female. They are doing this on animal species, and we are interested in the effect on those animals exposed to radiofrequency radiation.

We have collaborated with that organization by sending our scientists along with their scientists to investigate some of the industrial radiation facilities in the country, so that we have a better understanding of what the levels of exposure are in the working environment.

Our relationship has been primarily with our sister organization, the National Institutes of Occupational Safety and Health, which then translates that material to OSHA.

Senator FORD. Has the FDA made a total assessment of all sources of radiation exposure to man and the environment?

Has the FDA named those sources for agency review to determine the need for Federal standards or guidance?

Mr. VILLFORTH. In the context of your question, the answer is no, because we don't have authority for all of the sources.

We are not concerned with those radioactive materials which are under the control of the Nuclear Regulatory Commission. And we are not involved with nuclear powerplants or the sources of natural radioactivity found in the uranium tailings.

We have looked at those sources for which we have a direct responsibility under the FDA and under the Radiation Control for Health and Safety Act.

We have looked at those types of X-ray procedures which we feel need prioritizing because they expose large segments of the population.

So within our area of responsibility, we have attempted to do some prioritizing.

I might say that it is very difficult to do this when one deals with ionizing radiation and nonionizing radiation, since they produce different kinds of effects.

In the ionizing radiation area, which we give a top priority, we are concerned not only with the somatic effects to the individuals exposed and the effect to the fetus, but we are also concerned about the genetic consequences, the consequences to future generations.

We don't have that same concern for the nonionizing radiations because we don't have a genetic contribution or in some cases a teratogenic contribution from the nonionizing radiations.

Because of the more insidious aspect of ionizing radiation, we have made this our top priority. That is our No. 1 priority in the Bureau, and that is where we are focusing our attention.

Senator FORD. The committee is aware that EPA and BRH have been unable to agree on the limits of their respective roles in establishing Federal guidelines to other agencies on the use of ionizing radiation in medicine.

However, a memorandum of understanding appeared in January, I believe, in the Federal Register, signed by the two agencies.

Has this cleared up the jurisdictional disputes between those two agencies?

Mr. GARDNER. I don't think it has completely cleared up the problem. There is a difference of opinion between us, and the effort to resolve that difference of opinion is not over. It was slowed down by a change in administrations. At the present time, Dr. Kennedy, the Commissioner of FDA, and Mr. Costle, the Administrator of the EPA are discussing the matter.

I am sure it will work out satisfactorily. But they need more time. I would not look on an honest and legitimate difference in views as being a problem that would prevent both agencies from applying themselves to doing their jobs.

Senator FORD. In your opinion, what are the proper roles of the two agencies in protecting the public from unnecessary radiation from all sources?

Mr. GARDNER. What do I consider as the proper roles?

Senator FORD. What do you consider, yes, I am asking you.

Mr. GARDNER. I consider the roles as they are now defined to be an appropriate division of responsibility. Our job is to look after the products that are produced, and used in the medical and healing arts, and some of the consumer and industrial applications, and those are for the most part within the public health domain. And they are the right sort of activities to be included in our administration, which is a part of the Public Health Service.

Senator FORD. Do you think these jurisdictional disputes serve the public interest?

Mr. GARDNER. Not if they are carried out for any prolonged period of time and get in the way of doing the job.

Jurisdictional disputes will be inevitable as long as the world has to be divided up into pieces for effective management. They can, on occasion, be useful because they illuminate areas of disagreement and can result in a more effective way of doing a job.

They are not disruptive, unless they are allowed to become personal disagreements. And I don't think that is the case between ourselves and the Environmental Protection Agency.

Senator FORD. When do you think this will be settled?

Mr. GARDNER. Well, I would say by the end of the summer we ought to be able to resolve that. That is a function of Dr. Kennedy and Mr. Costle, being able to get together and discuss that matter.

Senator FORD. Do you think October 1 will be the end of summer?

Mr. GARDNER. That is the end of summer, yes, sir.

Senator FORD. If it is not settled by then, do you think you need an act of Congress?

Mr. GARDNER. I don't think so.

Senator FORD. Or you need a tough referee.

Mr. GARDNER. If it is not settled by then, I think someone else will step in and settle it.

Senator FORD. That is what I am getting to.

The committee asks your opinion on a proposal to establish the record systems to monitor individual radiation exposure for medical treatment.

You responded and I quote, "The performance of X-ray examinations will be affected substantially if all exposures had to be measured and recorded."

Why should the performance be affected?

Mr. VILLFORTH. I don't remember the context in which we answered that question. But we were concerned in that this proposal which has been discussed over the past 15 years was an attempt to relate medical radiation dose through some system of recordkeeping.

The problem has been that one cannot measure the dose adequately from these procedures. However, one can record the type of examinations that one receives, and in fact, this is something that we are testing in the Bureau of Radiological Health, right now.

For example, we have developed a patient record card which will allow us to record the date and the type of examination that we have at a particular X-ray facility. I carry one myself.

I visited the naval medical center last week and I recorded the data of the X-ray examination I received. The purpose of this is so that when another X-ray is requested of me or when I see another physician or if I am transferred, I can remember the details of the previous examination. The purpose, therefore, would be to tell the new physician who is examining me, where the previous exposure was conducted so that he will be able to request copies of those X-rays and thereby possibly eliminate the need for new X-rays.

The purpose of such a program, of registering or recording in your wallet or your purse or whatever some indication of your medical experience, is one of value, which we are testing in the form of a card ourselves, and we hope that is something that would be established around the country in order to cut down the amount of repeat examinations which are not necessary.

Senator FORD. I won't belabor but we may follow up on this. I have kept you long enough. But I do want to ask this one final question.

You indicated in your earlier responses that current medical malpractice environments and so-called defensive medicine contributes to unnecessary X-ray examinations.

And you stated, I believe, as an assumption that one-third of all X-ray examinations are unnecessary. The resulting cause to health care is about $2 billion annually.

This $2 billion annual increase in cost should disturb us.

Do you have any recommendations as to how this rate of exposure and economic waste can be reduced?

Mr. VILLFORTH. In terms of the question of the unnecessary ordering of the X-rays, it has been reported in the literature that about one-third of all medical X-rays might be unnecessary. The real question, aside from the concerns of medical—legal use of these X-rays, aside from the concerns of whether a physician is taking the X-ray because the patient demands it and the physician feels he is under some pressure from the patient, for whatever reason, it is very important to obtain a basis for efficacy, a scientific understanding for whether or not certain of these procedures are worth doing or not worth doing.

If I may use an example. We have had a small contract at the University of Washington Hospital to look at the misuse of X-rays of the skull taken on people who enter the emergency room of the hospital. It has been known for some time that there is a tendency to over-order or over-prescribe X-rays in emergency rooms.

You get a bump on the head, and the first thing they want to do is take an X-ray. The radiologist there said we feel that is not really effective. We are going to develop a list of criteria that must be met before we will order that X-ray. And we are going to test it.

These criteria were based on some experience and clinical impressions and so forth.

As a result of that project, we were very pleased to have a recent report from that same institution that they were able to reduce by

40 percent those skull X-rays without, in fact, any detriment to the patient.

In other words, with a little bit of education and with clear understanding of what were the indications before a skull X-ray should be taken, applying those indications, they could reduce by 40 percent the amount of skull radiographs.

Now, that is an impressive number. If you extrapolate that to the United States, we could probably save $40 to $50 million from skull X-rays alone throughout the United States. But the first thing that we need to do with that kind of an examination is to decide when it is efficacious, what are the criteria for a whole list of diagnostic procedures, from chest X-rays, to spine X-rays, or what have you.

That is a very difficult, timely, and perhaps very costly kind of testing that must go on. But we believe that that is perhaps one of the more fertile areas for reducing patient exposure.

We feel we have made a big contribution in equipment. We feel we have made some improvement in the technique, in the application. We can do more with proper quality assurance in conducting those examinations. But perhaps the largest area where we can achieve some success will be in the area of efficacy and the proper selection of the patient by the physician.

Senator FORD. If you establish that as a standard you would probably get into some professional problems.

Mr. VILLFORTH. Exactly. We have to do this with the total involvement of the professional community, the scientific community, and the clinical community. But we have to do it with some kind of data base. This does not exist now. There is no easy way of collecting this data. But it must be done. It is very important.

Senator FORD. Let me ask one final question.

With regard to the malpractice environment and the defensive medicine which you assumed cost $2 billion annually, could Congress by developing a malpractice statute assist in this problem and reduce the cost? Do you think that would be an effective thing for us to do?

Mr. GARDNER. I don't feel competent to answer that question, Senator Ford. I think that, appropriately that ought to be directed at the Secretary of the Department or perhaps the Assistant Secretary for Health.

Senator FORD. Well, you referred the cost, usually everybody can tell us the problems, but they have damn few solutions.

You are going to get in on this, aren't you?

Mr. MERRILL. Yes. That is a question that is closer to home. And I think we can do a little in this direction, and the kind of thing that Mr. Villforth talked about. If we are able to demonstrate that certain kinds of X-rays are not effective, that is going to have an impact on injuries across the country because the failure to perform one of those will no longer be held up as to the physician's carelessness. That is going to be slow and incremental.

That is a concern to us. It is a concern in other areas as well, this regulation in particular.

Senator FORD. Senator Stevenson, do you have some questions?

Senator STEVENSON. No. I have no questions.

Senator **Ford.** I thank you gentlemen for being here today.

As I stated earlier, we will have other questions for the record. Thank you.

[The following information was received for the record:]

Prehearing Questions of the Committee and the FDA Response

The Committee would appreciate receiving your views on the following items. You may deviate from the format set out below; it is intended to suggest the type of information the Committee wishes to include in the hearing record.

Question 1. The status of the development of emission control standards with respect to electronic products, including an estimation of the cost of this regulation for the current fiscal year, and fiscal year 1978.

Answer. Summarized below are the equipment performance standards in effect and under development by the Food and Drug Administration's Bureau of Radiological Health (BRH).

Equipment Performance Standards Presently in Effect

	Effective date
1. Television receivers	Jan. 15, 1970.
2. Cold cathode gas discharge tubes	May 19, 1970.
3. Microwave ovens	Oct. 6, 1971.
4. Diagnostic X-ray equipment	Aug. 1, 1974
5. X-ray baggage inspection systems	April 25, 1974.
6. Cabinet X-ray systems	April 10, 1975.
7. Laser products	Aug. 2, 1976.

Status of Standards Presently Under Development

	Date
1. Amendments to the Diagnotsic X-ray performance Standard	Ongoing.
2. Amendments to the Laser Performance Standard	Ongoing.
3. Microwave Diathermy Standard	Proposed rule, Sept. 1977.
4. Performance Standard for Ultrasound Therapy	Final rule, Aug. 1977
5. Performance Standard for Sunlamp Products	Proposed rule, July 1977.
6. Criteria for Mercury Vapor Lamps	Proposed standard, Nov. 1977.

In total, the BRH estimate of resources for support and development of radiation emission control standards for electronic products is:

Fiscal year:	*Million*
1977	$13.7
1978	14.1

Question 2: The status of Federal/State programs in ionizing radiation control and regulation, training of personnel, the inspection of old or new devices (particularly diagnostic devices); the status of the radiation incidents registry; procedures for updating and repairing old devices and new devices; procedures and status of inspection and certification of new devices to meet applicable FDA standards; manpower and funding needed to ensure proper calibration and other equipment standards in devices installed prior to the establishment and enforcement of FDA standards; the effectiveness of federal/state licensing and control of non-NRC radioactive materials.

Answer: *Status of Federal/State Programs in Ionizing Radiation Control.* The FDA's Bureau of Radiological Health (BRH) in cooperation with other Federal agencies (e.g., Nuclear Regulatory Commission and Environmental Protection Agency) has supported the Conference of Radiation Control Program Directors (representing the State radiation control agencies) in the development of the Ionizing Radiation Category of the Suggested State Regulations for Control of Radiation (SSRCR). The purpose of SSRCR is to assist the States in developing their radiation control regulations by providing a guide or model to encourage uniform regulations among the States, complement Federal regulations, and help States maintain regulations compatible with, identical to, or as effective as, Federal regulations. Because of requirements placed on State regulatory agencies in promulgating regulations consistent with the standards of a number of Federal agencies, it is especially important that Federal and State agencies cooperate in developing their regulations. The SSRCR has been prepared to be consistent with Federal radiation control regulations promulgated under authority of Federal laws (e.g., Atomic Energy Act of 1954, as amended, and the Public Health Service Act as amended, and the Radiation Control for Health and Safety Act of 1968).

The 1974 edition of the SSRCR is presently available to the States in development of their regulations and a revised edition will be completed in the next few months incorporating amendments to Federal standards promulgated since the last edition as well as other appropriate revisions.

TRAINING OF PERSONNEL

During the last two years, BRH training activities have continued to shift from the presentation of general radiological health training to that in support of specific program areas. For example, to support the Dental Exposure Normalization Technique (DENT) program, 116 State and local surveyors were trained in twenty (20) courses. The National Cancer Institute has provided the BRH with financial support to implement a mammography quality assurance program caled Breast Exposure: Nationwide Trends (BENT). This support has enabled the Bureau to train, in recent months, 87 employees of 18 State and local agencies in evaluating mammography exposures. Two courses trained 20 State and local agency personnel in the Nationwide Evaluation of X-Ray Trends (NEXT) program.

The BRH has also trained about 50 State and local personnel and about 100 Federal personnel in various aspects of basic radiological health principles, primarily in the safe use of radiation.

BRH personnel have also contributed to the training program of the Interagency Task Force on Training and Exercises, which seeks to develop the capability for dealing with emergencies at fixed nuclear facilities. Seventeen (17) planning and operational courses have reached a total of about 470 State and local people, and 12 exercises testing emergency response to plans have included 60 State and local personnel.

The BRH's Training Resources Center has provided general radiological health training material to the States. The recent release of the first three of a series of videotapes being produced especially for training purposes is expected to increase State and local demand for this type of help.

The BRH has also provided support to various universities in their efforts to provide training to State and local radiation control personnel as well as others. This training has been provided in x-ray control as well as nonionizing radiation control.

INSPECTION OF OLD OR NEW RADIATION-EMITTING DEVICES

For each performance standard, a compliance program is developed to insure and gauge compliance on the part of manufacturers with the given standard. These compliance programs to date have involved two types of testing of products manufactured in compliance with the standards. Products which are easily portable are obtained and tested in FDA laboratories. For these products, as well as less readily mobile products such as diagnostic x-ray systems, cabinet x-ray systems and laser products tests are also performed at either the manufacturer's plant or, with the owner's permission, at the owner's facility or site of use of the product.

Except for diagnostic x-ray systems and microwave ovens, products manufactured prior to the effective date of an applicable standard are not routinely tested. During the development of a performance standard extensive evaluation and assessment of the performance of products occurs. However, the Agency's inspection programs are largely confined to checking compliance with standards and thus are addressed to inspection of products certified to the compliant with the appropriate standard. Products are tested, however, which have been in use and not only when in new condition.

Seven (7) percent of the 2,700 annual diagnostic x-ray inspections performed by States are re-inspections of certified x-ray machines. The data obtained from these reinspections will give the Agency an information base to evaluate the compliance of these products over their useful life with the Federal performance standard.

In addition, the Agency's total data base of compliance inspection for diagnostic x-ray systems contains approximately 8% of uncertified (machines manufactured before the effective date of the standard) x-ray systems. The inspection of both certified (new) and uncertified (old) x-ray machines, and the comparison of such data will enable the Agency to evaluate the effectiveness of the standard in the reduction of unnecessary amounts of radiation.

STATUS OF THE RADIATION INCIDENTS REGISTRY

The Radiation Incidents Registry accumulates reports of human exposure to potentially injurious electronic product radiation. During the six years that the Registry has existed, data collected have been primarily in the form of case reports. These reports have helped to identify problems associated with radiation exposure of humans.

Underreporting and overreporting are two important limitations of case reports such as those in the Registry. In order to provide estimates and statistical projections, the population at risk must be known—this cannot be obtained from case reports, nor can case reports be used to estimate trends since the voluntary reporting of incidents is known to vary from year to year.

Reports of radiation incidents which have appeared in the professional literature are accepted into the Registry and regarded as public knowledge. However, this does not imply the acceptance of a cause and effect relationship or the conclusions reported in the literature.

As of May 1977, the Radiation Incidents Registry had catalogued data on 642 incidents reporting exposures to 1,108 persons.

Despite the limitations and problems associated with case reports, they have been useful in identifying two very important areas for the Agency: 1) the hazards associated with the use of ultraviolet radiation in dentistry; and 2) the hazards associated with broken mercury vapor lamps. In the case of ultraviolet radiation in dentistry, on two separate occasions, practicing dentists contacted the Agency for information regarding the injury potential that may have been associated with these devices. The inquiries initiated an investigation by the Agency that uncovered an additional 207 reports of alleged injury associated with a UV dental device. The regulatory action taken resulted in a corrective action program designed to provide the safest tool possible for the performance of the various dental techniques.

The first reported incident involving mercury vapor lamps occurred in a junior high school in Montgomery County, Maryland. This case report alerted the BRH to the problems associated with breakage of the outer envelope of mercury vapor lights. To date, sixteen (16) incidents have been reported alleging injury to 224 persons. The Agency will publish a safety standard for these lamps shortly. Through the early identification of these case reports, the Agency has been able to evoke a responsible attitude on the part of at least one manufacturer who now produces a lamp that poses a reduced hazard when broken.

In summary, the Radiation Incidents Registry is a voluntary reporting system composed mainly of case reports. These reports cannot be used for estimates, statistical projections, or to determine trends, since they have limitations in that they tend to under- and over-report incidents. Case reports can, however, identify problem areas associated with electronic devices and population groups that should be followed in epidemiologic surveys.

PROCEDURES FOR UPDATING AND REPAIRING OLD AND NEW DEVICES

The performance standard for diagnostic x-ray systems has provided a unique challenge as a result of the manner in which these systems are manufactured. Rather than being sold as a single item by a dealer or manufacturer, as is the case for most of the products regulated under the Act, diagnostic x-ray systems are often assembled at the point of use, frequently by a party different from the factory-based manufacturer and frequently from the components of more than one manufacturer. Such a method of manufacture has led to many interesting and complex questions concerning the identity and responsibilities of the manufacturer in these situations.

In anticipation of and in response to such questions, the performance standard for diagnostic x-ray systems and their major components recognized two types of manufacturers having responsibilities under the Act. These are the plant-based component manufacturer and the dealer or distributor, referred to as the assembler, who performs the final step in the manufacturing process and assembles or installs the various components to form a complete system at the site of use. A safe and properly functioning x-ray system depends on both parties performing their respective tasks correctly.

To preserve the radiation safety integrity and potential of diagnostic x-ray components manufactured in compliance with the performance standard for diagnostic x-ray systems, the Agency developed regulations concerning the assembly and reassembly of diagnostic x-ray systems which became effective coincident with the diagnostic x-ray equipment performance standard. This policy is found in Part 1000.16 of Title 21 of the Code of Federal Regulations.

The thrust of these regulations is to prevent the downgrading of the performance provided by x-ray systems manufactured after the effective date of the standard by preventing the assembly of pre-standard, uncertified components into such systems. Also, the policy on assembly and reassembly of diagnostic x-ray systems will prohibit the sale and assembly or reassembly of uncertified components after August 1, 1979. The continued use or repair of uncertified x-ray systems, however, will not be prohibited.

The effect of this regulation on the used x-ray equipment market and the purchasers of used x-ray equipment may be substantial. The Agency is currently reviewing the impact of this regulation in light of the experience with the x-ray standard and data on the x-ray equipment market. Completion of this evaluation will provide the basis for any revisions in this policy should they be warranted.

PROCEDURES AND STATUS OF INSPECTION AND CERTIFICATION OF NEW DEVICES TO MEET FDA STANDARDS

There are three (3) different program areas covered by the BRH in this particular area: (1) electronic products that are covered by FDA performance standards; (2) electronic products not covered by standards that are defective; and (3) medical devices used in radiological health care. The authority to regulate the first two areas falls under the Radiation Control for Health and Safety Act of 1968; the third area is covered under the authority contained in the Medical Device Amendments of 1976.

If a product is regulated by an Agency performance standard, a manufacturer must affix a certification label on that product to demonstrate that it meets the requirement of the applicable standard. In addition, the Agency maintains an ongoing compliance program for each electronic product for which a standard has been developed and put into effect, to routinely inspect products at manufacturing plants, at user sites, or at FDA laboratories. This depends on the size, assembly, etc. involved with each product. Special field or laboratory testing is conducted whenever the Agency becomes aware of a defective electronic product or an accidental radiation incident. The results of these tests can and have supported the Agency in any compliance actions against manufacturers.

The certification and inspection of medical devices used in radiological health care at the present time is uncertain. A mutual agreement with respect to the responsibilities under the Medical Device Amendments was reached in May of this year. The specific procedures regarding inspection and certification will be finalized following completion of the classification process currently being carried out.

Question 3. A summary of the problems perceived by FDA in enforcing its statutory mandate and need for manpower and funds to solve those problems; a general status report of population exposure to diagnostic and therapeutic radiation, including a discussion of allegations that increased diagnostic x-radiation is the result of many physicians' desire to avoid malpractice suits, and the effectiveness of educational programs to secure elimination of unnecessary radiation; discussion of controversy concerning the Environmental Protection Agency's efforts to set parameters for diagnostic radiation, including a discussion of any understandings between EPA and FDA in this area.

Answer.

SUMMARY OF PROBLEMS IN ENFORCING FDA'S MANDATE

In executing its compliance programs, the Agency has contracted with States to obtain data or compliance testing of medical x-ray units. Seven (7) contracts with States were first begun in FY 75 and an additional eleven (11) States were added in FY 76. All eighteen (18) States are continuing to perform inspections for FDA.

To date, the eighteen (18) States (including the District of Columbia and Puerto Rico) have inspected over 4,800 x-ray faciilties out of over 12,000 new certified installations within the eighteen contract States. This repreesnts an inspection rate of approximately 40% of the new installations. The present funding of the eighteen States totals to $303,000 per year and will be increased $325,000 this year, including the addition of three (3)—five (5) new contract States for a total of approximately 2,700 inspections.

A most promising development in the last three years has been the incorporation of Federally funded State inspections into the BRH's overall compliance program for medical x-ray equipment. The continued growth of this program is essential to effective enforcement of FDA standards. To maximize the effectiveness of this Federal/State partnership and maintain an adequate program of plant visits and in-house report reviews, the BRH estimates an additional annual resource requirement of $2.3 million, including 60 positions.

STATUS OF POPULATION EXPOSURE TO DIAGNOSTIC AND/OR THERAPEUTIC RADIATION

The X-Ray Exposure Studies of 1964 and 1970 indicated an annual increase of 3½ percent in the number of diagnostic x-ray examinations performed in the United States. By extrapolating this to 1977, we predict that 270 million medical and dental examinations will be performed this year. The 1964 and 1970 surveys were extensive studies that would be very expensive to repeat. However, the Bureau has an ongoing program (NEXT) to evaluate exposures from specific x-ray examinations. Data from NEXT indicate that patient exposure is remaining fairly constant for the majority of x-ray procedures, except for dental exposures, which appear to have decreased over the past four years. Although the NEXT system measures exposure from common examinations, it does not tract the numbers of different exams given.

Another BRH effort is underway to fill this void by establishing a continuing monitoring system in a representative number of medical facilities across the U.S. This program has the acronym "RED" for Radiation Experience Data. We expect to receive data from this system starting in January 1978. Meanwhile there are two areas, namely computed tomography (CT) and mammography with which the BRH is especially concerned. As computed tomographic units proliferate and examinations become more common, the population exposure from this relatively high-dose procedure will undoubtedly increase. A Bureau effort is currently underway to survey these units and to collect data in this rapidy expanding area. Regarding mammography exposures, the Bureau's BENT (Breast Exposure: Nationwide Trends) program monitors these exposures and provides an action program to reduce unnecessary exposure.

In the area of therapeutic radiation, approximately 300,000 persons are treated annually, with most of these treatments being for cancer. It is estimated that one-half of all cancer patients receive some form of radiation therapy. The Agency has several programs underway to evaluate the quality of therapeutic treatments. One of these programs is a survey of Cobalt-60 units in the United States to determine their capacity to accurately deliver a radiation dose under prescribed conditions and to identify sources of error. Preliminary results from 600 of these units indicate that 83 percent of facilities performed adequately, the remaining performances being marginal or clearly unacceptable. The unacceptable facilities were provided consultation and an opportunity to recheck their calibration after appropriate corrective action. A similar survey of some 350 medical accelerators is being planned. These efforts will lead to development of quality assurance programs and guidelines to obtain optimum benefits from treatment.

MEDICO-LEGAL PRESSURES ASSOCIATED WITH PRESCRIPTION OF MEDICAL X RAYS

Evidence that physicians are prescribing more x rays because of the medical malpractice situation comes primarily from literature references and polls conducted by professional societies. For example, in a January 12, 1976 article in *Medical World News* ("Defensive Medicine, How Much Diagnostic Overkill?"), the President of Blue Shield of California estimated that between 30–40 percent of current x rays have nothing to do with the patient's clinical requirements. In that same article, the American Academy of Pediatrics reported that in a survey of its membership half the respondents said they were ordering more x rays as a result of problems associated with professional liability.

While the literature is replete with articles that discuss in a general way the excessive use of x rays for medico-legal purposes, advice to physicians that they order excessive x rays also appears in some tests. *A Practical Medico-Legal Guide for the Physician* (Charles C. Thomas, publisher, 1973) recommends that "Any excessive number of x rays may be taken, but they are necessary to suport the diagnosis and to *protect the physician from a malpractice claim*" (emphasis added). The same text also recommends that "The private doctor may be forced to repeat x rays not only in order to treat the patient but also to protect himself from a possible malpractice suit. In this way he will be better equipped to justify his treatment of the patient later or when cross-examined at trial."

In summary, although we believe it is difficult to ascribe the requesting of an x-ray examination to purely defensive motives, we believe that the current malpractice environment does cause a number of unnecessary examinations to be taken. The ordering of unnecessary examinations is the greatest contribution to patient exposure and health care costs. Assuming that one-third of x-ray examinations are unnecessary for a variety of reasons, the cost to health care is $2 billion annually.

FDA EDUCATIONAL PROGRAMS FOR IMPROVING MEDICAL RADIATION USER PRACTICES

The FDA's Bureau of Radiological Health has a number of educational programs directed towards the reduction of unnecessary radiation exposure. Although it is difficult to directly measure the effectiveness of these programs, indirect evidence sugests that they are affecting radiation use. For example, a current educational vehicle used by the BRH, is the voluntary medical radiation recommendation. The first voluntary medical radiation recommendation developed and promoted by the Bureau provides guidance for x ray users on the use of gonad shielding in diagnostic radiology. Indirect evidence of success includes using data on sales of gonad shields and requests for a BRH explanatory booklet on the subject. Three of the most successful known manufacturers of shields have submitted sales data on two generic types of shields. Two manufacturers of "shadow" shields project sales increases (in one case an estimated 100 percent increase is forecast) in 1977 of 1,500 and 1,000 units respectively over 1976 figures. A producer of the shaped, contact shield has reported total sales over a three-year period of about 1,400 shields, with most sales occurring in the past year. Over 60,000 copies of the FDA publication, "Gonad Shielding in Diagnostic Radiology," have been requested and distributed since July 1975.

Another program in professional education is centered around the Radiological Health Sciences Laboraatory, a complex teaching system for medical students, radiology residents, and practicing physicians. Despite its high cost ($15,000), 49 medical schools currently have purchased and are using the system, with an additional 26 schools having units on order for delivery this year. Acceptance is so great, that we anticipate that a Learning Laboratory will be used in every medical school by 1980. One example of the effectiveness of early education of physicians is found in a recent Bureau pilot study where physicians were taught to use selection criteria in deciding whether or not an x-ray examination was warranted following trauma to head. Physicians who were exposed to education about the utility of the selection criteria before they began requesting x rays order 44 percent few exams than those who were exposed later in their careers.

Two operational programs administered by the Bureau are illustrative of the effectiveness of education programs. DENT (Dental Exposure Normalization Technique) is an exposure reduction and quality assurance program in the dental x ray area which includes educating dentists about optimum procedures for exposing and processing dental x-ray film. The DENT program is currently used by 37 Federal, State, and local radiation control agencies, responsible for about two-thirds of the dental machines in the United States. As a result of the program, agencies have been able to achieve an approximate 40 percent reduction in average exposure.

BENT (Breast Exposure: Nationwide Trends), is a similar program which deals with exposure reduction and quality assurance for mammography examinations. In a 1976 pilot study conducted in five States, the Bureau was able to identify facilities with unnecessarily high or inordinately low exposures and to effect corrective education programs through State agencies. With support from the National Cancer Institute, it is hoped that nationwide participation can be achieved over the next two years.

In the area of operator training, the Bureau has developed a multi-media packaged training program for radiologic (x-ray) technologists, entitled, *Radiation Protection During Medical X-Ray Examinations*. Five modules have now been developed and may be purchased from the National Audiovisual Center, GSA. A sixth on the topic of film processor quality assurance is expected to be completed by the end of 1977. To date, about 1,500 individual packages have been sold and 125 copies of each package are available for free loan from State and regional Federal rediological health programs. Data available on the packages indicate that a minimum of 10,000–12,000 individuals view this radiation protection material yearly.

In order to improve the radiation protection curricula in the approximately 1,200 American Medical Association-approved x-ray technology training programs, the Bureau developed a syllabus on radiation protection. This syllabus has recently been published as part of the American Society of Radiologic Technologists' Curricula Guide and will be incorporated in all the AMA-approved training programs, which have an enrollment capacity of 20,000 students.

A recently developed document which addresses the FDA's medical radiation educational programs in more detail is appended for the Committee's information.

Question 4. A general discussion of any other agreements or understandings between FDA and other federal agencies regarding sharing or transferring of responsibilities in the area of ionizing radiation.

Answer. The Bureau of Radiological Health (BRH) participates in a number of Memoranda of Understanding (MOU) and Interagency Agreements (IAG) with other Federal agencies and the Canadian Government. The context of these agreements and understandings encompasses a variety of activities such as: participation of other Federal agencies in a BRH operated system for measuring the effectiveness of diagnostic x-ray equipment and a program for correcting deficiencies, exchange of information on compliance program efforts; Radiological Emergency Assistance Plan, identifying authority and roles concerning imported products, research projects utilizing the particular expertise or facilities of another agency or participating in ongoing research programs, and providing sevices to other Federal agencies by monitoring personnel for radiation exposure.

A listing of Memoranda of Understanding and Interagency Agreements currently in force are listed below:

MEMORANDA OF UNDERSTANDING

Organ Dose Index System.—A system for measuring the effectivenes sof x-ray eqiupment during diagnostic radiology and the design of a program to correct observed deficiencies.

225–74–6005—Department of the Air Force, Office of the Surgeon General.

225–76–6001—Health Services Administration, Indian Health Service.

225–76–6002—Department of the Navy.

225–74–6004—To Identify Authority and Roles Concerning Imported Products—U.S. Customs Service, Department of Treasury.

225–74–6008—Establish Uniform Federal Standards for Electronic Product Radiation and Determine Compliance—Occupational Safety and Health Administration, Department of Labor.

225–75–6001—Exchange of Information on Compliance Program Efforts—Canadian Department of National Health.

225–75–6005—Radiological Assistance Plan—Energy Research and Development Administration.

225–75–6022—Testing of Electronic Products: Microwave Ovens—Federal Communications Commission.

INTERAGENCY AGREEMENTS

224–72–6024—Calculation of Internal Organ Doses from External X-Ray Beams—Energy Research and Development Administration.

224–73–6027—Sale and Distribution of Training Packages Produced by Bureau of Radiological Health—General Services Administration.

224–74–6016—Neonatal Hyperbilirubinemia and Brain Damage in Childhood—National Institutes of Health.

224–74–6041—Teletherapy Source Calibration Survey—National Bureau of Standards.

224-75-6002—Evaluation of Laser Protective Eyewear—Airforce School of Aerospace Medicine, Brooks Airforce Base.

224-76-6004—Establish Standards and Methodology for Measuring Incoherent Light Sources—National Bureau of Standards.

224-76-6005—Support of Contract to Coordinate Federal/State Radiation Control Activities Etc.—Environmental Protection Agency.

224-76-6009—A Follow-up Study of Persons Who Had 131 and Other Diagnostic Procedures During Childhood—Nuclear Regulatory Commission.

224-76-6001—Mammography Quality Assurance Program—National Institutes of Health, National Cancer Institute.

224-77-6002—Support of Training for Radiological Emergency Response Planning—Nuclear Regulatory Commission.

224-77-6003—Workshop on Physical Basis of Microwave Interactions with Biological Systems—Office of Naval Research.

224-77-6007—Develop Miniature Hydrophones for Pulsed and Continuous Wave Ultrasound—National Bureau of Standards.

PERSONNEL MONITORING SERVICES

224-76-6010—U.S. Coast Guard.
224-76-6011—Bureau of Prisons Medical Programs.
224-76-6012—National Institute of Mental Health, St. Elizabeths Hospital.
224-76-6013—Health Services Administration, Division of Hospitals & Clinics.
224-76-6014—Environmental Protection Agency.
224-76-6015—Center for Disease Control.
224-76-6016—National Institutes for Occupational Safety and Health.
224-76-6017—U.S. Capitol Police.
224-76-6018—Health Services Administration, Indian Health Service.

Question 5. A summary and status of ionizing radiation research, including funding and manpower levels; efforts to develop individual dosimeters; reactions to proposals which would require that individual radiation exposure records for medical treatment be maintained; status of recommendations for radiation dosage in medical treatment.

Answer.

SUMMARY OF IONIZING RADIATION RESEARCH

The BRH supports several studies of the effects of exposure to ionizing radiation. These will be considered under three headings: (1) exposure of adults to x-rays, particularly at low levels; (2) exposure to x-rays in very early life; and, (3) exposure to radioactive iodine.

Exposure of Adults to X-Rays

Studies of adult exposure to x-rays include breast cancer as a result of multiple fluoroscopies and of treatment of postpartum mastitis and risk benefit analyses of the use of mammography for breast cancer screening. Results from these studies have played important roles in the mammography screening controversy.

Long term follow-up studies of occupational exposure of United States Army x-ray technologists and of physician members of the American College of Radiology permit study of mortality of both groups. In addition, analyses of morbidity and of reproductive and genetic effects of radiation exposure of the radiologists are in progress. An early finding is that radiologists and their families have much greater exposure to medical x-ray than do a comparable group of specialist physicians (pathologists). In another study leukemia patients and controls are compared as regards exposure to diagnostic x-rays.

An experimental study of dose response aspects of the induction of chromosomal aberrations is underway. A study of differential tissue sensitivity to x-rays has been approved.

Exposures to x-rays in life is the subject of one grant supported study of infants who had x-ray treatment for enlargement of the thymus. Leukemia has been shown to be excessive in this group. There is another study of children who were exposed to soft x-rays for removal of their hair in the treatment of ringworm of the scalp (tinea capitis). An excess of thyroid tumors from 6.5 rad exposures was detected as were excesses of salivary gland and skin cancers. Various measures of brain function also appear to be affected. A study of possible endocrine effects in the females of this group as manifest by reproductive performance has been proposed.

Exposure to X-Rays in Early Life

In a collaborative study being conducted by the National Center for Health Statistics, the use of ionizing radiation during pregnancy will be ascertained for a sample of late fetal deaths and for live births. By comparing the frequencies of prenatal exposure in the fetal death vs. live born groups, possible associations may be detected. This is an unusual opportunity to determine whether fetal deaths are more common when exposure to x-ray and nuclear medicine procedures has occurred. Childhood cancer mortality is the subject of a large scale British study of parental preconception, prenatal and childhood exposures to ionizing radiation. Susceptability to death from other causes as a result of a pre-leukemic state is also under investigation.

In an experimental study exencephaly has been produced in CF1 mice with exposures as low as 5 R. Fetal growth and biochemical development after in utero x-ray exposure is also being studied.

A large long-term effects study of beagle dogs is designed to compare the effects of exposure to low levels of x ray at different ages including preconception and prenatal exposures. Effects on the development of normal renal tissue have been reported. Various malignancies have been found in the exposed but not in the control dogs.

Exposure to Radioactive Iodine

Exposure to radioactive iodine (I^{131}) is involved in three studies: an experimental study comparing the carcinogenicity of x-rays and I^{131}, and two studies in people. In the first human study, a large group of children who were exposed to I^{131} before 1968 for diagnosis of thyroid disease will be sent a questionnaire to determine whether they have developed thyroid tumors. Comparison groups will be similarly studied. Collaboration in this study involves the Nuclear Regulatory Commission, the National Cancer Institute and the Environmental Protection Agency. The second human study is of a group of women who were treated for hyperthyroidism with I^{131} vs surgical removal. Mobidity and mortality will be compared to determine whether there is an increased risk of developing neoplasms of non-thyroid tissue particularly of the breast. In the rat study dose response aspects and the possible synergistic effects between irradiation of the thyroid and pituitary glands will be determined.

The annualized BRH resource level for ionizing radiation research is $1.6 million, including 9.5 man-years.

INDIVIDUAL RADIATION EXPOSURE RECORDS/INDIVIDUAL DOSIMETERS

Proposal to establish record systems to monitor individual radiation exposure resulting from medical treatment have received frequent consideration in the past. The major question associated with such a proposal is how it would serve to reduce unnecessary exposure. Would a patient be denied a needed x-ray examination if his/her cumulative exposure exceeded some predetermined level? The BRH has already become involved in guidance programs that indirectly respond to this issue and which have obvious potential for limiting patient exposure from diagnostic x-ray examinations.

For instance, an in-house pilot test of an X-Ray Record Card is currently being conducted. Although no attempt is made to quantify examination exposures, this Card system is designed to increase the awareness of both physician and patient of the latter's medical radiation exposure history. Also, to meet a very practical need, the BRH's "Selection of Patients for X-Ray Examinations" document presents typical exposure data for an extensive list of examinations.

A number of technical problems would confront any attempt to follow through on a record-keeping project. Acceptable definitions of exposure limits and measurement parameters (e.g., skin entrance or mid-line exposures, specific organ dose estimates) would have to be reached. The performance of x-ray examinations would be affected substantially if all exposures had to be measured and recorded. On balance, the inherent variability of equipment and user techniques makes user education a better tool for reduction of unnecessary exposure. The BENT program, discussed in the next item, illustrates the value of voluntary user programs.

STATUS OF RECOMMENDATIONS FOR RADIATION DOSAGE IN MEDICAL TREATMENT

At the recommendation of the FDA's Medical Radiation Advisory Committee, the BRH is investigating the feasibility of developing ranges for skin entrance or organ doses for specific diagnostic x-ray examinations. Information is being accumulated in preparation for publication of a Notice of Intent in the Federal Register which will invite comment on all pertinent aspects of this issue. Ultimately, recommendations outlining optimum exposure limits will be closely allied with current Bureau activities in the general area of quality assurance. Two specific programs (BENT and DENT) which were discussed earlier indicate that the BRH can be effective in reducing radiation dosage for selected x-ray examinations.

The Bureau of Drugs is responsible for the establishment of the amount of radioactive material to be administered to a patient which has been shown to be safe and effective for the intended use. Suggested or recommended amounts of radioactivity to be administered are included in the package inserts for NDA approved radiopharmaceuticals. The BRH conducts clinical evaluations of radiopharmaceuticals and nuclear medicine instrumentation directed toward achieving safe and effectvie procedures at the lowest possible patient radiation exposure. The BRH prepares voluntary guidelines for radiopharmaceutical applications. This information is utilized in the preparation of package inserts. The FDA recognizes that a physician must be free to use a drug for an indication or at a dosage not specified in the insert when such usage appears to be rational and for the best interest of the patient. This was the clear intent of Congress when it wrote the Food, Drug, and Cosmetic Act and its amendments and has been repeatedly stated as FDA policy.

Question 7. A discussion of topics similar to those set out above as they relate to the development of standards in the area of nonionizing radiation. We would appreciate particular emphasis on the status of research on health effects and current knowledge regarding low level effects of microwave radiation; the development of standards and/or guidelines for use with respect to ultrasound diagnostic devices, lasers, etc.; other research and regulatory programs in the area of nonionizing radiation.

Answer.

EQUIPMENT PERFORMANCE STANDARDS FOR NONIONIZING RADIATION PRODUCTS

In addition to the performance standards that have been discussed previously, all nonionizing radiation electronic products manufactured since October 18, 1976, are subject to the defect provisions of the Radiation Control for Health and Safety Act. When a defect as defined by the regulation is discovered, the manufacturer is notified and required to comply with the requirements of the Act. An example of this type of compliance case was the finding by FDA of a defective ultraviolet dental appliance that emitted unnecessary ultraviolet radiation which could expose the user (dentist or dental assistants) and the patient. The manufacturer recalled all 25,000 units and appropriately modified the product.

STATUS OF FEDERAL/STATE PROGRAMS IN NONIONIZING RADIATION CONTROL

In the nonionizing radiation category the Bureau of Radiological Health has worked with the State personnel in development of Suggested State Regulations for Lasers. It is expected that a draft will be available for widespread review by September 1977.

PROCEDURES FOR UPDATING AND REPAIRING OLD AND NEW DEVICES

The questions of repair of certified products and of assembly of component parts has also been addressed by the Agency with regard to laser products. Like x-ray systems, but to a lesser extent, laser products are sometimes manufactured in component fashion. The guidance furnished manufacturers of laser products was contained in a letter to manufacturers of these products dated June 23, 1976. As with the other products subject to performance standards, the laser standard does not control repair of laser products or apply ot products manufactured prior to the effective dat eof the standard.

Microwave ovens manufactured prior to the effective date of the performance standard (October 8, 1971) must comply with the then applicable voluntary industry standard. When the BRH determined that most manufacturers had some ovens that were not complying with this voluntary standard a program was established with each manufacturer to voluntarily bring each oven into compliance with the standard. This program has continued over the years and when an oven not subject to the performance standard is found exceeding the industry standard, the particular unit is called to the attention of the manufacturer who then corrects the oven.

For ovens subject to the performance standard a manufacturer is required to provide service instructions that when followed will assure that the oven complies with the performance standard. These service instructions are reviewed by FDA personnel as a part of the manufacturer's submittal of the testing and quality control program upon which he bases his certification. Should an oven be found that fails to comply with the requirements of the Microwave Oven Performance Standard, the manufacturer is obligated by the Radiation Control for Health and Safety Act to either repair, replace, or refund the cost of the product at no charge to the consumer.

USE OF DIAGNOSTIC ULTRASOUND DEVICES

Ultrasound radiation is utilized in therapeutic and diagnostic medical applications. FDA surveys have indicated that approximately 50,000 ultrasound therapy units are in currnet use throughout the nation resulting in as many as 37.5 million treatments per year. Typical ultrasound exposures range from 1 W/cm^2 to 10 W/cm^2. Field measurements have shown that these units are often poorly calibrated. After extensive laboratory investigation, the FDA has recently published a draft equipment performance standard to improve calibration and labeling of these devices.

Within the past few years, diagnostic ultrasound has become an important clinical tool in obstetrics, cardiology and diagnostic radiology. Growth rates in sales are on the order of 25 percent per year. A recent FDA survey indicated that there were approximately 500,000 ultrasound examinations of pregnant women in 1974.

Typical ultrasound exposures from these devices range from 1 mW/cm^2 to 100 mW/cm^2 ultrasound is inadequate to determine any potential risk associated with this modality. The Food and Drug Administration is investigating the need for equipment performance standards to be applied to this modality. Efforts are also being made to improve the professional training of the users of diagnostic ultrasound, both physicians and technologists, and to examine the application of this modality as a possible substitute for diagnostic procedures using ionizing radiation.

ULTRASOUND BIOLOGICAL EFFECTS RESEARCH

When the BRH ultrasound bioeffects research was initiated less then five years ago, almost nothing was known about the potential risks associated with medical ultrasound applications. Much of the earlier experimental work in ultrasound bioeffects from intensities well above those used in medicine, had little applicability for risk assessment. In the Bureau, an exposure facility was designed to produce precise, reproducible continuous wave exposure conditions. This facility has been utilized for exposing pregnant animals, Drosophila (fruit fly) pupae, cell suspensions, solutions of nucleic acid bases, and human blood. All exposures have been in the intensity range of medical (diagnostic and therapeutic) ultrasound. Examples of some of the effects studied and reported to date include: release of serotonin from human platelets, modification of human platelet morphology, and decreased in vitro recalcification time (clotting time) after exposure to as low 65 mW/cm^2 intensities of continuous wave ultrasound; increased postpartum mortality and reduced fetal weight in mice exposed in utero; and developmental changes in Drosophila pupa. Effects reported by Bureau grantees include chromosome aberrations and altered growth rate in plant cells and roots after exposure to continuous wave ultrasound and increased incidence of anomalies in mice exposed in utero to high intensities of pulsed ultrasound.

The epidemiologic program examines some of the potential risks associated with use of diagnostic ultrasound in humans. The current effort is focused on exposure of the fetus and includes analysis of existing data, in collaboration with the National Institutes of Health and the National Center for Health Statistics, and the British Medical Radiation Council. Such data, although not intended to document the relative risks and benefits of diagnostic ultrasound, may provide information useful in the design of future epidemiologic studies. In addition, the BRH has contracted for a controlled follow-up study of eight and nine year old children who were exposed prenatally to diagnostic ultrasound and an equal number of unexposed children. As resources permit, there is a need for controlled clinical trials to provide estimates of possible risks, as well as benefits, of the use of diagnostic ultrasound in amniocentesis, in fetal imaging and detection, and in fetal monitoring during delivery. Experimental investigations will be required at low ultrasoud intensities and with pulsed ultrasound, such as that used in pulse-echo diagnostic equipment. Developmental effects need validation. The development of blood clots after ultrasound will require testing, and examination of possible ultrasound-induced phlebitis should be undertaken. Suggestive evidence that ultrasound exposure interferes with the immune system represents an additional current indication of need for elaboration of current research.

MICROWAVE BIOLOGICAL EFFECTS RESEARCH

Prior to the adoption of a microwave oven standard, a thorough review of the available biological information was conducted. This indicated that two major organs, the eye and the testes, were susceptible to microwave damage. The research data showed that damage to these organs was primarily thermal in nature and consequently associated with microwave exposures of 100 mW/cm^2 or above.

Since that time, research information has continued to accumulate. Biological effects are now being observed at substantially lower levels. The scientific community in this country are reporting a wide variety of microwave effects at 25 mW/cm^2 or less; some studies are reporting effects at less than 10 mW/cm^2.

Microwave effects in animals at relative low exposure levels include changes in the morphology of the brain, changes in the chemistry and also the electrical activity of the brain. A breakdown of the normal physiological barrier between the blood and the brain has also been reported. Behavioral changes associated with low-level microwave exposure include disruption of discrimination, behavioral suppression, avoidance of the microwaves and decreased stimulus control of behavior. Effects on hormone levels such as thyroxine have been observed in animals subjected to microwaves.

A recent report indicates that microwave exposure produces a suppression of the immune system. Suppression could compromise an organism's ability to counteract infections. Microwave exposures have been shown to alter both the red and white blood cells. The effects include lymphoid cell changes, increased blastic transformation, erythropoetic and lequopoetic changes, as well increases in the number of red blood cells and altered cell membranes. The alterations of white blood cells suggest that so-called auto-immune disease, such as some types of arthritis or lupus, may be promoted by microwave exposure.

The BRH has at this time an active research program in microwave bioeffects, divided into six program areas:

(1) *Dosimetry.*—Characterization of RF/microwave exposures in biological specimens.

This study is to determine the energy absorbed by both experimental subjects and phantom human bodies. Also to determine low-level microwave effects on the metabolic rate of mice.

(2) *Developmental effects.*—The effects of chronic low-level microwave exposure on growth and development.

This study examines the impact of chronic low-level microwave exposure during gestation on the prenatal and postnatal development of rats.

(3) *Behavioral effects.*—The effect of microwave exposure on a number of behavioral measures.

This study examines the effect of microwave exposure on classical conditioning, learning, memory, and discriminative stimulus control as well as drug interactions.

(4) *Genetic and reproductive effects.*—The effects of microwave exposure on mutagenesis, chromosomes, and reproduction.

This study investigates survival and mutagenesis in bacteria, chromosome structure in cultured cells, testicular changes, and teratological problems.

(5) *Cataractogenesis.*—The effect of microwave exposure on the lens and biochemistry of the eye.

This study of microwave cataractogenesis focuses on four major areas, i.e., dosimetry around the eye, microwave cataract histopathology, biochemistry, and possible non-thermal effects.

(6) *Human epidemiology.*—There are two human epidemiologic studies relating to microwave exposure, one nearing completion and the other will soon begin. A study of 40,000 naval veterans of the Korean War compares mortality, military and V.A. hospital experience, and disability claims of those exposed to radar and control groups during a 20-year followup period. There is interest in extending this study to investigate illnesses and hospitalizations outside military and V.A. hospitals and in determining the health status of offspring of the study population. The second study will compare the reproductive histories (fertility, sex ratios, fetal mortality, and congenital malformations of offspring) of 2,000 male physical therapists who use microwave diapthermy equipment with their counterparts who do not use such equipment.

Biological effects of microwave exposure has accumulated and show effects at lower levels than earlier supposed, and effects on organs other than the eye and testis, as additional research is accomplished. The information is being gathered through animal experimentation, so clear knowledge of human hazard and disease is not yet available. However, suggestive information relative to health effects of concern to humans has been obtained, so that microwave-associated disease is no longer necessarily limited to cataracts in eyes and temporary sterility of exposed males. Clarification of the issues in microwave radiation hazards evaluation awaits completion of additional research.

LIGHT BIOLOGICAL EFFECTS RESEARCH

The BRH involvement with ultraviolet, near ultraviolet, visible and infrared radiations, (known as light) includes a research program in bioeffects.

The current bioeffects research activity is based primarily on the need for certain types of information which are considered necessary for either providing information or for evaluating information to provide a complete basis for safety considerations. For ultraviolet radiation, the primary target organ is the skin, with burns and erythema being the common responses for acute exposure and with skin cancer being the major hazard from chronic exposure. Indeed, skin cancer is the most common form of cancer in humans. A major effort is currently being initiated to collect all the information in the scientific literature and to consult with scientific experts in this area to develop a documentation of the known factors which render ultraviolet radiation hazardous and to decide upon acceptable safe levels for exposure.

At the same time laboratory experiments are being conducted which will provide necessary information with regard to the effects on mammalian cells and mutagenesis, carcinogenesis, and recovery processes. This information can then be used for any BRH activity with regard to electronic products which emit radiation in the ultraviolet region.

Similar approaches are being utilized for determining the bioeffects of near-ultraviolet exposures. The near-ultraviolet region is currently of great interest because there is little definitive information available and because many electronic products of the fluorescent lamp type which emit near-ultraviolet radiation which is probably irrelevant to their functions and which may be hazardous.

Sensitization which arise either from genetically controlled conditions or from chemicals in foods and drugs can be very important for effects from exposure to near-ultraviolet radiation. Such synergism can lead to photosensitization which can lead to severe burns and cancers as with ultraviolet radiation alone and which can be used medically to treat certain diseases such as psoriasis and herpes simplex infections.

Near-ultraviolet radiation can also produce effects beneath the skin. These effects are sometimes called extra-visual effects because they are not mediated through the eye. A well-known example is the production of Vitamin D. Other effects on hormones have been documented in birds. While extra-visual effects are suspected in man, little is known about which wavelengths are responsible or what the photoreceptors are. Since most people spend the majority of their time in artificial light, these factors should be explored so that intelligent decisions about the ideal environment to create where we live and work. Thus, this area of research should be expanded.

Because of the large number of sources of potentially injurious sources of ultraviolet radiation, it is critical all of the available information on hazards be evaluated. Such an evaluation will serve to definitively outline the areas of needed research such as noted above. The evaluation will also serve to provide a basis, known to industry and government alike, upon which the hazards of any particular product can be determined.

Visible radiation acts primarily through the eyes. Damage to the eyes was shown to be particularly important for radiations from lasers since the radiation beams are highly focused. Laboratory experiments are in progress to investigate physical damage caused by burns on the retina and to investigate functional damage as shown by decrements in visual acuity are particularly important for the diffuse, non-coherent visible radiation sources such as desk lamps, where long-term exposure to intensely lighted surfaces may cause permanent loss of visual acuity.

The epidemiologic studies effort in light is focused on exposure of the newborn. We are now into the fourth year of two collaborative studies with the National Institutes of Health. The one is a randomized clinical trial of the use of phototherapy for neonatal jaundice. Data from examinations of the infants during the neonatal period are being analyzed. A detailed one year follow-up examination is nearly complete. Provisions to stay in contact with the children are being made and there are plans to re-examine them at five years of age. Both benefits and risks from this use of phototherapy will be estimated. Another study consists of analysis of the data from the large Collaborative Perinatal Study conducted several years ago by the National Institutes of Health. The objective is to estimate the magnitude of short and long term risks from exposure to newborns to intermediate bilrubin levels. Reduction of these risks can presumably be accomplished by phototherapy.

The infrared region of the light radiation area has had little scientific investigation with regard to bioeffects. Heating is known to occur at the skin and below, and this effect has been used medically for some time. Another concern of epidemiologic studies staff was exposure of newborn infants to the infrared and visible light associated with the radiant warmers used in intensive care units and nurseries. These devices have been designated as Class 3 product; i.e., they must be shown to be safe in order to be sold after some future date. In view of available resources we do not plant epidemiological studies pending resolution of the Class 3 designation. The bioeffects of infrared and near-infrared radiations is an area where scientific research will be needed.

BRH FUNDING AND MANPOWER SUPPORT OF NONIONIZING RESEARCH

The annualized BRH resource level for nonionizing radiation research is $2.2 million including 41 man-years.

Question 9. Brief summary of BRH activities in international programs.

Answer. The Bureau of Radiological Health has an international reputation for its regulatory, educational and research programs in the field of medical and consumer product radiological health. In recognition of the Bureau's expertise, the World Health Organization (WHO) has designated the BRH as a Collaborating Center for Standardization of Protection Against Nonionizing Radiation, a Collaborating Center for Training and General Tasks in Radiation Medicine, and a Collaborating Center for Nuclear Medicine. The BRH has exported the entire NEXT (Nationwide Evaluation of X-ray Trends) system to Canada and Italy, and is currently processing NEXT data from Israel. The countries of Australia, Mexico, and the Netherlands are currently considering adopting the NEXT system as well. The countries of Israel, Australia, Germany and Algeria have ordered Radiological Health Sciences Learning Laboratories which were developed by the Bureau. In addition, other countries have expressed interest, and the list of countries participating will undoubtedly increase. The Bureau has contracts with scientists, in other countries, such as Dr. Alice Stewart in England who is conducting a world famous study on the effects of obstetric radiography on children. The Bureau frequently has visiting scientists from other countries work at its facilities.

The BRH conducts correspondence with scientists in other countries concerning various aspects of its programs. Currently, for example, the Bureau is discussing its proposed recommendation regarding x-ray examination for women of childbearing age with scientists and clinicians in England where the "ten day rule" system has been nationalized. The BHR represents papers and educational sessions about its programs at international meetings. Recently, Bureau personnel spoke at the Paris, France meeting of the International Radiation Protection Association (IRPA) concerning its BENT and DENT programs, as well as its studies on bone marrow determination. This fall, BRH personnel will present a summary of its quality assurance in radiology programs at the International Congress of Radiology in Rio de Janeiro.

Under HEW's Special Foreign Currency Program, the FDA currently supports eight radiation research projects in Poland and Yugoslavia.

Question 10. Any other comments which FDA might like to offer to highlight achievements and/or perceived problem areas.

Answer. We would like to submit for the Committee's information the enclosed report entitled, "The Bureau of Radiological Health: A Look at FDA's Program to Protect the American Consumer From Radiation." This report provides a succinct overview of the FDA's major regulatory and voluntary efforts in the area of radiation control, and examines the impact of the Agency's programs to eliminate unproductive radiation exposure to the American consumer/patient.

Throughout the FDA, there is recognition of the need for science as a basis for regulation. Protection of public health and safety is the fundamental objective of the Agency's regulatory program.

The success of the BRH in its public health actions is based on establishment of the need for standards, development of valid biological and engineering bases for standards, and ability to enforce corrective action programs for products which pose a threat to public health and to the safety of an individual.

The BRH, through its highly focused research competence, has been able to develop scientific information, to evaluate research data from others, and to offer significant scientifically based advice to other organizations.

Scientific information developed through research by the BRH is represented by research aimed to support standards and guidelines, such as:

(*a*) Establish the existence of effects of microwave radiation on protein synthesis and on chromosomes, in support of the microwave oven standard.

(*b*) Show pre-cancerous changes as a result of exposure to ultraviolet radiation, in support of both the laser and sunlamp standards.

(*c*) Show chemical sensitization of individuals to light to produce adverse effects, including increased susceptibility to pre-cancerous changes.

(*d*) Develop information about radiation dose relative to diagnostic image quality, in support of the diagnostic x-ray standard.

(*e*) Establish the potential for production of congenital anomalies in the very early stages of pregnancy, in support of development of guidelines for irradiation during pregnancy.

(*f*) Demonstrate thyroid cancer after 6.5 rad doses, in support of the linear dose-response model for radiation protection guidelines.

Evaluation of research knowledge is a necessary part of initiation of standards or guidelines, as well as the enforcement of corrective action programs for products which pose a threat to public health and safety. Examples of research evaluation include:

(*a*) Research on mammography and breast cancer provided the basis for a risk/benefit analysis of mammographic screening for breast cancer.

(*b*) Evaluation of existing data of thyroid tumors and leukemia in humans indicate that the linear model of the dose-response relationship can be validated.

(*c*) Research on ultraviolet effects provided the basis for corrective action program for a dental device.

(*d*) The review of available low dose information on microwave effects provided a basis for corrective action programs for microwave ovens out of compliance with the standard. During the reviewed literature of research performed in the United States, it became apparent that three-fourths of the low dose studies were performed with the direct support of the BRH.

Scientific advice to other organizations has resulted in significant impact on health-related programs, with examples such as:

(*a*) Planning of the bioeffects studies associated with the Department of Transportation evaluation of supersonic transport overflights (Climatic Impact Assessment Program).

(*b*) Data on breast cancer in patients after multiple fluoroscopies and the risk/benefit analysis of mammographic screening for breast cancer provided impetus for reevaluation of the National Cancer Institute programs for routine screening of asymptomatic women.

(*c*) Collaboration between the Nuclear Regulatory Commission, the National Cancer Institute, the Environmental Protection Agency, and the Food and Drug

Administration has been developed for evaluation of risks of Iodine–131, as a result of BRH expertise in epidemiology.

(*d*) A short course for National Cancer Institute staff on the biological effects of ultrasound was presented by BRH experts.

BRH research programs therefore provide direct and indirect support for regulatory standards and guidelines, and impact on programs in other agencies. Research activities are concentrated in the ionizing, microwave, medical ultrasound, and light areas. Research initiatives into radiofrequency radiation, magnetic fields, airborne ultrasound, and infrared hazards await satisfactory completion of the current programs.

Question 11. With respect to the annual recommendation made by the Bureau of Radiological Health that the Act of 1968 be amended to eliminate the required submission of an annual report, the Committee would like to know if other information could be added to the report which would be helpful to the Congress in evaluating progress made under the Act, or would some change in format make the report more useful both to the Bureau of Radiological Health and the Congress? The Committee believes the data are useful now, and would like to inquire as to what the problem is with the requirement to prepare and submit the report.

Answer. A prinicipal reason for recommending the elimination of the annual report required under The Radiation Control for Health and Safety Act of 1968 is that the same kind of information can be, and frequently is, included in the annual report of the FDA. The FDA annual report corresponds to the fiscal year while the report required by the Radiation Control Act, of 1968 corresponds to the calendar year. One result is an unnecessary duplication of effort and use of resources which contribute little if anything to Congress' knowledge of achievements and activities under The Radiation Control Act beyond what would be available in the FDA annual report. The appropriate substantive items specified for reporting by the Radiation Control Act could be included in the FDA's annual report in an appropriate section of the report. The FDA also prepares a quarterly report which is available on request. The FDA appreciates the fact that the data provided in the report under the Radiation Control Act has proved useful, but suggests that the same information results could be achieved with less cost by including such information in the FDA annual report.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., September 9, 1977.

HON. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportaion, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in further reply to your May 31 letter to Commissioner Kennedy in which you requested certain information regarding radiation health programs.

As you know, we earlier provided you with answers to most of the questions included in that letter. We have enclosed the answers to the remaining questions.

If you have any further questions, please contact me or Mr. Banks of my staff at 443–3793.

Sincerely yours,

ROBERT C. WETHERELL, Jr.,
Director, Office of Legislative Services.

Enclosure.

Question 2. The status of Federal/State programs in ionizing radiation control and regulation, training of personnel, the inspection of old or new devices (particular diagnostic devices); the status of the radiation incidents registry; procedures for updating and repairing old devices and new devices; procedures and status of inspection and certification of new devices to meet applicable FDA standards; manpower and funding needed to ensure proper calibration and other equipment standards in devices installed prior to the establishment and enforcement of FDA standards; the effectiveness of Federal/State licensing and control on non-NRC radioactive materials.

Answer.

MANPOWER AND FUNDING NEEDED TO ENSURE EFFECTIVE PERFORMANCE OF RADIATION-EMITTING DEVICES MANUFACTURED PRIOR TO FDA STANDARDS

Data is not available on the number of medical and dental x-ray machines that were manufactured prior to the issuance of the FDA standards. Furthermore, it would be difficult to precisely estimate the number of old systems in use because some of them become subject to the Federal standards when they are upgraded with certified components. However, we estimate that there are a total of 250,000 existing medical and dental x-ray machines in use in the United States and that the average cost of the inspection of each machine would be $125 if contracted to State agencies.

Question 3. A summary of the problems perceived by FDA in enforcing its statutory mandate and need for manpower and funds to solve those problems; a general status report of population exposure to diasgnotsic and therapeutic radiation, including a discussion of allegations that increased diagnotic x-radiation is the result of many physicians' desire to avoid malpractice suits, and the effectiveness of educational programs to secure elimination of unnecessary radiation; discussion of controversy concerning the Environmental Protection Agency's efforts to set parameters for diagnostic radiation, including a discussion of any understandings between EPA and FDA in this area.

Answer.

EPA'S MEDICAL RADIATION RECOMMENDATION SETTING ACTIVITIES

The Environmental Protection Agency, acting under its interpretation of its authority (42 U.S.C. 2021(h)). is developing medical radiation guidelines for implementation in Federal agencies. It is the FDA's position that the EPA authority extends only to hazards of atomic energy radiation (such as fallout) as is delineated in the U.S. Code; responsibility for radiation applications in the healing arts, as well as development of applicable guidelines remained with the Bureau of Radiological Health, FDA, under the terms of the President's Reorganization Plan No. 3 of 1970, Section 2(a)(3).

HEW officials (Secretary, Assistant Secretary for Health, Commissioner of Food and Drugs, Director, Bureau of Radiological Health) have taken strong exception to EPA attempts to develop and promote guidance for radiation applications in the healing arts. FDA believes that present EPA activities regarding medical radiation guidance is inconsistent with the principles of sound and effective resource management. The formulation of medical radiation recommendations under the guise of the Federal Radiation Council authority, not only constitutes a duplication of effort charged to HEW (FDA) by P.L. 90-602, but also fosters confusion among states and the medical community by obscuring HEW's responsibility and role in setting national health care policy for radiation in the healing arts. Moreover, EPA's recommendations, applicable in the Federal sector, could seriously compromise or hamper FDA's program to develop public health guidelines which must take into account the broadest and most varied of health care needs, in addition to the necessity for continuity and conformance with overall health policies as enunciated by the Department.

HEW/EPA AGREEMENTS CONCERNING MEDICAL RADIATION ACTIVITIES

In an effort to mitigate health risks and repetitive interagency debate while a permanent solution was being sought at a higher level, HEW Under Secretary Marjorie Lynch and EPA Administrator Russell Train agreed in December 1976 that the two agencies would prepare and sign a Memorandum of Understanding (MOU), outlining a temporary modus operandi regarding development of medical radiation recommendations. The MOU became effective on January 18, 1977. EPA did not follow the terms of the agreement when it published medical radiation recommendations in the *Federal Register* on January 26, 1977, and publishing and distributing a document entitled "Radiation Protection Guidance for Diagnostic X Rays." Discussions are currently underway between the current FDA Commissioner, Donald Kennedy, and the current EPA Administrator, Douglas Costel, in a further effort to seek a satisfactory solution.

Question 6. Any reactions to the recommendations (1) for requiring licensing and/or certification of radiologic technicians, and (2) that federal radiation activities be clarified or consolidated within a single regulatory agency.

Answer.

LICENSING AND/OR CERTIFICATION OF RADIOLOGIC TECHNICIANS

The FDA recognizes that an integral part of controlling unnecessary radiation exposure to patients is the improvement of those individuals responsible for the safe and effective use of radiation. Regardless of the quality of the equipment available, x-ray personnel can exercise considerable influence over the total dose and overall diagnostic quality image. The selection of x-ray techniques and the practice of beam restriction are outside the scope of equipment standards or regulations, and yet can have a profound effect on the exposure patients receive from radiologic examinations. Limited information obtained from FDA/State surveillance activities on the actual job performance of x-ray personnel indicates that (1) overall performance of x-ray personnel, whether or not they are credentialed, is not optimum; and (2) credentialed persons perform somewhat better than non-credentialed individuals. The FDA's Bureau of Radiological Health has made significant strides in improving the overall radiation protection practices of these persons through multimedia training packages, the development of a syllabus on radiation protection for use in x-ray technology schools, the presentation of training courses for x-ray instructors, etc. FDA is limited however in the number of technologists it can reach through such voluntary channels. At least one-third of the estimated 150,000 technologists actively employed are not credentialed and thus do not fall under any system.

An additional problem is that standards are not uniform even among the various State and professional certification organizations. We, therefore, believe that it is vital for us to collaborate with State agencies, elements of the private sector and other Federal components in the development of a comprehensive set of national standards. Such standards could serve as the framework for licensing programs conducted by the States, professional certification programs, as well as a basis for third-party reimbursement, such as under Medicare. The FDA's plan to develop suggested national standards for radiation equipment operators is consistent with the recommendations presented in an HEW report on health manpower credentialing recently signed by Secretary Califano.

We cannot endorse the approach to technologist licensure as embodied in legislation presently before the Congress. We believe that licensing is a legitimate State function; the Federal Government's role should be that of a convenor of State and other interested parties for the purpose of establishing standards, which if universally adopted, wil ensure uniformity and effectiveness in safeguarding public health.

> "The FDA intends to vigorously execute its charge to develop comprehensive national credentialing standards for medical radiologic personnel, utilizing the approach outlined in the HEW report."

CONSOLIDATION OF FEDERAL RADIATION ACTIVITIES

The FDA believes the consolidation of Federal radiation activities into one agency will give the appearance rather than the fact of effectiveness. It is our belief that the principal result of consolidation will be a monolithic structure that will seriously constrain the abilities of the components of such an agency to deal effectively with problems arising from the various forms and applications of radiation: health care delivery, research, industrial and commercial applications, for example. Expertness in one field of radiation (ionizing, nonionizing, light or sound) does not guarantee expertness in other forms of radiation. Concentrating all radiation activities into one agency would not alter that condition. Expected savings in manpower and dollars as a result of consolidation could be an illusion. Furthermore, the creation of a single radiation agency at the Federal level would bring together under one direction such diverse activities as the promotion and development of new technological applications of radiation, on the one hand, and the promotion of radiation safety and analyses of the efficacy and safeness of such new devices on the other hand. While there may always be a problem of divided responsibilities and shared interest in the field of radiation, the FDA feels it would be more protective of the public welfare to improve coordination among all kinds of radiation activities at the Federal level so that various interests might work together with greater consistency and effectiveness toward the common good. There are examples of this in the radiation field: for example, between the NRC and FDA—the former in the licensing of byproduct materials for use in medical devices, and the latter being responsible for evaluating the efficacy and safety of medical devices using byproduct materials.

Question 8. The status of regulation and standard setting under the new Medical Devices Act. Are there any potential problems or conflicts with the Radiation Control for Health and Safety Act of 1968?

Answer:

STATUS OF FDA REGULATION OF MEDICAL DEVICES

The Medical Device Amendments of 1976 (Public Law 94–295) were enacted into law on May 28, 1976. The result of this legislation provides significant new and expanded authorities to the Food and Drug Administration to control or eliminate hazards associated with all medical devices. Because this is new legislation, many of the efforts to date have been directed at developing and implementing procedural requirements called for by the amendments. Such regulations include those dealing with classification, registration, premarket notification, investigational device exemptions, etc., to name a few. In terms of standard setting activities, one must recognize that under the Medical Device Amendments, the first process that must be followed is that of classification. This is a process by which FDA, through the use of advisory committees, determines the appropriate level of control for products based in the risk hazard potential associated with these products. The alternative classifications are class III (premarket approval), class II (standards), or class I (general controls). The clasification process is ongoing right now by FDA and its advisory committees. It is expected that this project and process will be completed sometime during fiscal year 1978. Once the classification process is complete, we will have an information base to determine needs and priorities and we will be able to proceed with development of standards.

POTENTIAL CONFLICTS BETWEEN THE MEDICAL DEVICE AMENDMENTS AND THE RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968

There are no unsolvable problems or conflicts between the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act and the Radiation Control for Health and Safety Act of 1968. We in FDA have examined the authorities, functions, and responsibilities and made assignments to assure coordination of activities.

The Radiation Control Act of 1968 gave the FDA authority to develop and administer equipment performance standards for radiation-emitting medical devices; the Medical Device Amendments of 1976 gave the Agency the added authority for determining the safety and efficacy of all medical devices, including those that emit radiation in carrying out their purpose. The new amendments also gave the Agency authority to restrict the use of medical devices, again including radiation-emitting medical systems, a type of control not available under the relatively limited authority of the Radiation Control Act of 1968.

A SUMMARY OF MEDICAL RADIATION PROTECTION EDUCATIONAL PROGRAMS OF THE BUREAU OF RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

SECTION I. BACKGROUND AND GENERAL DESCRIPTION

A. The Bureau's Program To Improve Radiation Users

The Bureau of Radiological Health conducts a number of activities aimed at upgrading the radiation protection practices of individuals who use radiation-producing, equipment, particularly in the healing arts. These activities comprise a vital complement to the Bureau's efforts to improve the performance of the equipment itself. Motivating radiation users to understand the need for protecting patients against unnecessary radiation exposure and providing them with the knowledge and skills necessary to do so is essential, for experience has shown repeatedly that even the best equipment can be grossly misused by poorly trained operators.

These user-directed programs have two basic functions: (1) to upgrade the performance of radiation users through setting guidelines for desirable user practices, improving curricula in professional and technical schools, promoting continuing education of practitioners and their staffs, and assisting State and local jurisdictions in carrying out their own radiation protection responsibilities; and (2) to provide training services to FDA, other HEW components, and State and local agencies, including upgrading the job skills of people with radiation protection responsibilities.

B. Biological Basis for a User-Oriented Program

The importance of improving user proficiency is stressed in a report "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," prepared by the National Academy of Sciences–National Research Council (NAS–NRC) in 1972. The report points out that exposures from diagnostic medical procedures are the major source of radiation to the public and that they can be greatly reduced at little cost and with little sacrifice of the associated medical benefits. The report stresses than any increase in radiation exposure will result in a corresponding increase in deaths and illnesses and, conversely, a reduction in exposure can lower this toll.

C. How Well Are Radiation Users Performing at Present?

The NAS–NRC report states that overall dose to the body can be reduced as much as 30 percent by improved techniques on the part of x-ray machine operators, chiefly through limiting the size of the x-ray beam to an area no larger than the film. This is corroborated by data collected by the Bureau from x-ray surveys conducted across the nation by State and local radiation control agencies (see Nationwide Evaluation of X-ray Trends under Section II.A). The data show that operators of x-ray machines often fail to properly restrict the size of the x-ray beam. The data further indicate that, as a result of poor operator practices, the radiation dose to the male reproductive organs resulting from x-ray examinations of the lower back can vary by a factor of 2,000 times from facility to facility depending upon the protective techniques employed by the operator of the machine. Another recent study, in Rhode Island, demonstrated the radiation doses to patients from dental x-ray examinations can be reduced by more than half through a program of educating dental personnel, chiefly in the proper method of processing films (see Dental Exposure Normalization Technique under Section II.C).

D. Public Attention to Radiation Use and Misuse

In *Silent Slaughter*, a nontechnical book for the lay public (similar to *Silent Spring*) published in 1972, the authors summarize the problem of x-ray user performance as follows: "The lack of training in radiation protection that characterizes much of the medical and dental profession . . . is the single most important factor in the whole x-ray problem." The authors also attempt to create a public awareness of radiation hazards. In nontechnical terms, they correctly point out that excessive exposure to x-rays can cause leukemia and other forms of cancer in children and adults, congenital defects (if delivered during prenatal life), and lifespan shortening.

The book's main theme is that, although radiation is a valuable tool, much of man-made radiation (especially diagnostic radiation) is excessive and can be avoided.

In 1974, a publication titled *Medical and Dental X-Rays: A Consumer's Guide to Avoiding Unnecessary Radiation Exposure*, by Priscilla Laws, was published by the health research group of Public Citizen, a consumer organization under the auspices of Ralph Nader. Included in the publication are specific questions which individuals can ask their physicians, dentists, and x-ray technologists concerning the indication for the examination and the adequacy of protective practices. In 1977, Dr. Laws published a book titled *X-Rays: More Harm Than Good?*, which supplements the information in the earlier publication with a more detailed analysis in which the problems associated with the use of diagnostic x-rays are considered from the perspective of both patients and health workers.

Mammography has recently been the subject of public attention for several reasons. A number of public figures had mastectomies which were widely publicized; nationwide, the use of mammography subsequently increased. Also, a well-publicized controversy has arisen over the relative risks and benefits of the mammographic examinations included in the National Cancer Institute's Breast Cancer Detection Demonstration Project, conducted at 27 medical centers throughout the country.

E. Types of User-Oriented Activities

The Bureau's educational programs aimed at improving the radiation protection competence of radiation users will be described in Section II. These activities fall into seven basic categories: (1) assessing the nature and magnitude of the problem by estimating the radiation dose received from various specific examinations, and by ascertaining medical radiation trends; (2) developing and promoting voluntary medical recommendations; (3) developing and promoting the use of x-ray quality assurance measures; (4) reaching radiation users through upgrading the teaching of radiation protection in professional and technical schools, and through promoting and conducting continuing education for users already in practice; (5) educating consumers of radiation services; (6) helping to establish standards for user qualifications, generally implemented through other agencies; and (7) strengthening the ability of State and municipal radiation control agencies to improve user practices on a local level.

SECTION II. SPECIFIC ACTIVITIES

A. ASSESSING USAGE TRENDS AND PATIENT EXPOSURE

Nationwide Evaluation of X-Ray Trends

With both financial and technical support from the Bureau, a combined State-Federal Task Force on the Nationwide Evaluation of X-Ray Trends (NEXT) has developed a system for measuring the effectiveness of State and Federal regulatory agency activities directed at reducing patient radiation exposure during diagnostic radiography. The system, which is called the Organ Dose Index System, was successfully pilot-tested during the spring of 1972. It has been adopted by 39 States, 4 local governments, a professional society, a foreign government, and 7 Federal agencies (the 3 military services, U.S. Coast Guard, Bureau of Prisons, U.S. Public Health Service, and Indian Health Service).

The system, designed to serve as an adjunct to the State or agency's X-ray installation inspection program, is based on measurements of the patient exposure and the x-ray dose to the reproductive organs that would be received by a "standard patient" during the radiographic procedures most frequently performed at each x-ray facility. Data are collected using survey procedures, forms, and test equipment standardized by the Task Force.

The data outputs from the system permit users to compare mean values for reproductive organ dose, exposure at skin entrance, beam size, and other parameters for radiographic exams performed by practitioners in their State or agency with those for all other users of the system before and after the implementation of programs developed in response to P.L. 90–602.

The information derived to date from the system shows a wide variation in patient exposure and gonad dose values for specific x-ray examinations. Much of this variation is due to poor practices on the part of x-ray machine operators..

Study of the Efficacy of the Pelvimetry X-Ray Examination

One possible source of unnecessary radiation exposure is the use of x-ray examinations which may not be efficacious, i.e., examinations which do not materially affect the diagnosis or medical management of the patient. Only large-scale statistical studies can establish the efficacy of a given x-ray procedure. A beginning has been made in this direction through a joint project with the Obstetrical Statistical Cooperative of New York, which has computer-stored records on a large number of obstetrical cases. In this study, the usefulness of the pelvimetry x-ray examination was analyzed. The results of the study, which raised questions concerning the efficacy of the exam, were published. Further investigations will be made.

Live-Patient Study of Dental X-Ray Doses

In its communication with dentists, the Bureau seeks to recommend x-ray techniques which will minimize radiation exposure to the patient. In order to formulate valid recommendations, it is first necessary to ascertain the radiaton doses actually received by patients from various x-ray techniques and procedures.

A project has been completed in cooperation with the Public Health Service Hospital in Baltimore in which miniature radiation-measuring devices were placed in and around the mouths of patients during typical x-ray examinations. The results of this study have assisted the Bureau in formulating recommendations for dental x-ray practice.

Front-End Analysis Project

The term "Front-End Analysis" has been used to define the process of determining the true causes of job performance problems before attempting solutions to the problems. In this study of x-ray technologists, data are collected on personal background characteristics (e.g., training, experience), supervision (e.g., type of medical specialty, supervisor attitudes toward radiation protection) work environment (e.g., workload, type of facility), and job performance. The data are analyzed to determine what factors, or combinations of factors, appear to have the most significant effect on either good or poor performance. Information obtained will be useful to BRH other Federal agencies, and the private sector in designing more effective programs to improve the quality of medical radiographic services.

In 1976, a pilot project to design and test a survey methodology was completed, through a contract, using a sample of 300 medical x-ray operators in Maryland, Virginia, and the District of Columbia. The survey methodology will be applied to a national study in 1977.

B. DEVELOPING AND PROMOTING VOLUNTARY MEDICAL RECOMMENDATIONS

Recommendations vs. Regulations

In July 1976, the Bureau of Radiological Health undertook a new educational effort with the publication of a voluntary medical recommendation concerning the use of specific-area gonad shielding. This activity, because of its voluntary nature and because it is concerned with user practices rather than equipment specifications, is significantly different from the Bureau's more familiar regulatory responsibilities. These recommendations are intended to provide health practitioners with guidance, which they can apply according to their own judgment, about various issues affecting the radiation exposure of patients.

Three important observations constitute the philosophical basis for this effort: (1) the people who refer patients for x-ray procedures and those who operate the x-ray equipment and ancillary equipment to produce the diagnostic information have a controlling influence over their patients' radiation exposure; (2) these health professionals must exercise professional judgment about the care of their patients, taking into account the unique circumstances of each individual; and (3) there are important, unresolved medical radiation issues which merit investigation and resolution.

Steps in Developing a Recommendation

The medical radiation recommendations are developed with the input of all parties concerned with the practice of diagnostic radiology—referring physicians radiologists, technologists, medical physicists, radiological health authorities, educators and consumers. In the case of the gonad shielding recommendation, the participants included the American College of Radiology, as well as other professional and scientific groups. The formal procedures for developing recommendations are similar to those for regulations; however, broad-based participation in the recommendation process is especially important to help ensure the acceptance and cooperation of all parties in implementing the recommendations, which are intended both to inform and to motivate.

Once it is decided to propose a recommendation, the radiological community is informed of the recommendation process by several means: (1) the Federal Register; (2) Bureau mailing lists; and (3) professional journals. The Federal Register, which regularly publishes accounts of government activities, first carries an Advance Notice of Intent to Propose Recommendations. Next, the proposed recommendations are published in the Federal Register. After a period for written comments from concerned parties and after a reevaluation of the proposal on the basis of the comments received, the Federal register announces the final recommendations.

A procedure based upon achieving consensus among various interests is lengthy and painstaking, but has the advantage of openness at all stages. Background materials prepared in the course of developing each recommendation may include: (1) an Environmental Assessment Report, which carefully examines the potential costs and benefits of the recommendation; (2) a Documentation Report, which considers the overall ramifications of a recommendation and presents biological evidence associated with the problem; (3) overview papers which outline available information and suggested approaches to medical radiation issues; and (4) reports of pilot studies, clinical trials, or other pertinent research.

Implementation

Publication of recommendations in the Federal Register is not the end of the program of voluntary recommendations; it is only a step toward implementation. To be of benefit, the recommendations must be promoted. Although the means of doing this may vary somewhat with the nature of the individual recommendation, the primary emphasis will be on professional education—both formal and informal. For example, recommendations will be incorporated in the various learning packages the Bureau makes available to medical and allied health schools. The Bureau will also present the recommendations at professional meetings and in professional journals. Whenever appropriate, the Bureau will work with professional societies, local radiation control agencies, consumer organizations, and the media to further disseminate the recommendations.

Recommendations under Development

In addition to the Specific-Area Gonad Shielding Recommendation, the Bureau is developing the following recommendations:

(a) Medical Radiation Exposure of Women of Childbearing Age;
(b) Use of the Routine Chest X-Ray Examination;
(c) Use of the Skull X-Ray Examination for Trauma;
(d) Selection of Patients for Dental X-Ray Examinations;
(e) Medical Radiologic Technologist Qualifications; and
(f) Quality Assurance in Diagnostic Radiology.

C. DEVELOPING AND PROMOTING QUALITY ASSURANCE PROGRAMS

DENT (Dental Exposure Normalization Technique)

What is DENT?

DENT is an exposure reduction and quality assurance program for radiological health agencies. The health agency sends x-ray exposure cards to all dental x-ray facilities; these are exposed by the dentist and returned for analysis. Facilities which show excessive exposure are then visited to demonstrate the changes in exposure and processing necessary to produce diagnostic-quality radiographs with minimum patient exposure.

Background

Studies of intraoral x-ray examinations have shown exposures at the skin ranging from 100 to over 5,000 mR per film. Consequently, a study was conducted by the Bureau to empirically determine the exposures required for quality dental radiographs. A series of radiographs was produced at selected kVp settings from 50 to 90 kVp, using a dental phantom. The range of exposures at each kVp setting was great enough to produce films too light to be of diagnostic value at the lower exposure levels and too dark to be diagnostic at the upper exposure levels. Subsequently, a panel of dentists was able to establish a range of exposures which will produce acceptable radiographs at each kVp setting.

Results of DENT

The DENT program is currently used by 37 Federal, State, and local radiation control agencies, responsible for about two-thirds of the dental machines in the United States. Twelve of these agencies have completed Phases I and II; data reported by nine of them show that approximately 43 percent of the machines in Phase I were visited because of high exposures. As a result of the followup surveys, the nine agencies were able to achieve an average exposure reduction of 240 mR per film, or approximately 41 percent. Recently, the American Academy of Dental Radiology endorsed DENT as an effective exposure reduction and quality assurance program.

What DENT Can Accomplish

1. Significant reduction in unnecessary exposure from conventional x-ray procedures. (DENT is not applicable to panoramic and cephalometric radiology.)
2. Optimum exposure procedures for dentists whose exposure per film is excessive, thus assuring consistent, quality radiographs for better patient care.
3. Motivation of dentists and auxiliaries to practice good radiological health.

Demonstration Project at Baltimore PHS Hospital

The Bureau is conducting a program in cooperation with the Public Health Service Hospital in Baltimore to assess the results of initiating procedures for assuring consistent radiographic quality. This is the Bureau's first attempt to demonstrate the impact of a facility-based quality assurance program in a radiology department.

The project is divided into two phases. The first phase, which ran from February through June, 1975, involved the collection of baseline data on such parameters as repeat x-ray examinations, radiographic film quality (as determined by the radiologist), and patient exposure. During the second phase, various quality assurance procedures are being introduced into the hospital's radiology department. These include techniques for monitoring the performance of film processors, x-ray machines, and radiologic technologists. As these procedures are implemented, Bureau personnel will continue to collect and evaluate data to assess the effectiveness of the program.

To date, evaluation of the data after implementation of processor quality assurance has demonstrated the value of this part of a quality assurance program. By improving processor performance, a reduction of 30 percent was achieved in the department's retake rate. X-ray machine output monitoring is currently being developed and evaluated. As a result of the pilot program's success to date, similar programs are planned at other PHS hospitals.

Pilot State-Based Program in West Virginia

This pilot study was performed by the Bureau in cooperation with the American College of Radiology and the West Virginia State Department of Health. It was designed to test the feasibility of State radiation control agency implementation of a voluntary program for quality assurance in diagnostic radiology. The specific questions addressed were: (a) whether existing quality assurance test tools and methods are adaptable to State programs and resources, and (b) whether such programs are readily accepted by local facilities, physicians, and technlogists.

A team of representatives from the West Virginia Radiological Health Program and the Bureau first performed preliminary surveys in which they visited a limited number of facilities in West Virginia to perform a varety of quality assurance tests on their x-ray equipment. The tests included a sensitometric check of the processor and determination of film-screen contact, technique factor accuracy, and x-ray machine output reproducibility.

The survey protocol was then revised to make it more effective and acceptable and retested through a larger series of surveys.

The results of the West Virginia pilot study indicate the desirability of implementing similar programs on a wider basis. Thus, the Bureau has begun working with a task force on quality assurance established by the Conference of Radiation Control Program Directors. To assist States in instituting quality assurance programs, the task force is developing a procedures manual.

BENT (Breast Exposure: Nationwide Trends)

Background

A recent study of mammography practices indicated that approximately 20 percent of facilities performing mammography had unnecessarily high exposures as a result of poor film-processing techniques (Bicehouse, 1975). In 1976, the Bureau, together with the District of Columbia Bureau of Institutional Hygiene and Radiological Health and the Pennsylvania Bureau of Radiological Health, completed pilot studies of a program to lower exposures by identifying and correcting poor techniques; pilot studies were also begun in Massachusetts, New Hampshire, and Minnesota. The program utilizes dosimetry cards to enable the State or agency to identify unnecessarily high and inordinately low exposures and to establish priorities for their efforts to lower exposure and/or improve image quality. Data are also collected on equipment, technique factors, recording media, and characteristics of patients receiving mammograms.

Results

As a result of the successful completion of the pilot tests in the District of Columbia and Pennsylvania, and subsequent support of the program by the National Cancer Institute, the program is being offered to all States during 1977–78. In the completed pilot tests, facilities with unusually high exposure were generally found to be using improper film processing or insufficient filtration in the x-ray beam; their image quality was probably adequate. In facilities where exposure was abnormally low, the radiologists tended to be dissatisfied with image quality; in many cases image quality was significantly improved by increasing the exposure to a level more usual for the image receptor in use.

In the initial trials, the BENT program proved to be an effective method for identifying facilities which use exposures that seem inappropriate for mammographic examinations. In addition to reducing exposures that are too high, it can increase those that are too low and might be inferior for diagnosing early breast cancer. Cooperation of the radiologists who have been visited in the program thus far has been encouraging and suggests that the BENT program will be as successful as the DENT program.

D. EDUCATING RADIATION USERS

Radiological Health Sciences Learning Laboratory

More than 300,000 physicians currently practice in the United States. Most of them either use diagnostic radiology themselves or rely heavily on its benefits. They are directly responsible for ordering the examination of the patient, overseeing the conduct of the examination, interpreting the results, and applying this interpretation to the health care of the patient. Through a Bureau conract, the University of California at San Francisco has developed a learning system to teach all these elements of x-ray usage, including the radiation protection aspects, to medical students. This system, called the Radiological Health Sciences Learning Laboratory, is directed at the the three phases of the radiologic examination, and interpretation of the results.

All medical students, as future selectors of patients for radiographic examinations, should be trained in the elements of patient selection; these are presented in a series of lectures in the Learning Laboratory. Students who will be radiology residents, and other future physicians who plan to supervise the use of radiographic equipment, should be acquainted with technical aspects of the actual performance of radiographic examinations. This material is covered in a series of lectures and laboratory experiments designed to be used with a special x-ray machine and a manikin. All physicians who will be involved in interpretation of radiographic examinations and the use of this information in patient diagnosis and treatment need training in the interpretation of radiographs. The learning file, which is a part of the Learning Laboratory, provides simulated clinical experience with 1200 documented radiographic cases in self-teaching format, reproduced on full-size x-ray film. The system is now being made available at cost to medical schools through the American College of Radiology; thus far, more than 75 institutions have purchased it.

Gonad Shielding Program

The genetic damage which can result from irradiation of the reproductive organs can be significantly reduced through the use of gonad shielding, particularly during examinations in which the gonads are in the direct x-ray beam, such as procedures involving the lower abdomen, pelvis, and hip. Surveys have shown that utilization of these devices in medical practice is presently low, and the Bureau has undertaken an educational program to correct this situation. Through a contract with the Bureau, the University of California developed a new concept in male gonad shielding which employs a shaped shield contained in a carrier garment which the patient can don and remove himself. This shield, which is now available commercially, has been clinically tested, and the implementation phase of the project is currently underway. With the cooperation of the American College of Radiology, a sample shield was distributed to each U.S. radiologist, along with an informational pamphlet produced by the Bureau. The pamphlet has since been revised and is being distributed extensively to x-ray users. Other types of specific-area gonad shields (e.g., shadow shields) have also become commercially available.

Shields, carriers, and informational materials have been distributed to hospitals and clinics of the Public Health Service, Indian Health Service, and Coast Guard. Also, the U.S. Army is planning to purchase gonad shields for use in its medical facilities. It is anticipated that routine use of shields in these various facilities serve as a model of good practice.

The Bureau has published a guideline on shielding in the Federal Register. This guideline was codified in Part 1000 of Subchapter J of Chapter I, Title 21, Code of Federal Regulations.

Further implementation plans include encouraging revision of training curriccula for x-ray technologists to include appropriate training on the use of shields, as well as publication of shielding articles in professional journals. The ultimate goal of this program is to achieve the use of male gonad shielding during appropriate examinations of all men and boys from infancy through the procreative ula for x-ray technologists to include appropriate training on the use of shields years. Shielding of the female gonads (ovaries) is much more difficult because of their anatomical location. As the technology required to protect the ovaries becomes available, a parallel action program to promote female shielding will be undertaken. (Part of the Bureau contract with the University of California at San Francisco involves a study of ovarian shielding.)

Medical Radiation Exposure of Pregnant and Potentially-Pregnant Women

Some 800,000 pregnant women are x-rayed annually in the United States. Current systems for scheduling these women for x-ray examinations (e.g., the ICRP 10-day rule, the NCRP 14-day rule) either are not being implemented or, when implemented, are believed to cause more harm than they purport to avoid. The Bureau is currently developing recommendations for the management of these patients, and has investigated the efficacy of pelvimetry, an examination which presently accounts for 70 percent of direct-beam exposures to embryos or fetuses. As a part of the recommendation development process, the Bureau published a report "Clinical Methods of Avoiding Medical X-Ray Exposure of the Human Embryo and Fetus: A Technical Overview."

Dental X-Ray Training Manikin

In many schools which train dentists, dental hygienists, and dental assistants, it has been the practice to use fellow students and other individuals as practice patients in the study of oral roentgenology. Many of these practice radiographs are not used for diagnostic purposes and thus result in unnecessary exposure to ionizing radiation. Consequently, the Bureau contracted to have the Alderson Company in Stamford, Connecticut, design and construct a manikin, called the Dental X-ray Teaching and Training Replica, to replace human practice subjects. After testing and evaluation, an improved model was developed; this model has been offered for sale by the company since 1968. To date, more than 500 have been sold to approximately 400 teaching institutions.

The manikin consists basically of a human skull with polyurethane foam "flesh" and latex "skin," as well as a trongue of the same materials. A mechanical arm and finger are provided to hold dental films. The entire assembly hooks over the back of a dental (or other) chair and has a jaw that can be opened, closed, or locked in any position.

The use of this manikin can improve dental x-ray teaching programs not only by eliminating exposure to humans, but also by making possible unlimited radiography of a standard subject for perfecting technique and for experimentation.

Study To Develop Training in X-Ray Science and Engineering

The goal of this contract at Oregon State University was the development of a training program at the undergraduate level to provide engineering, premedical and predental students with a basic background in x-ray science. In 1971, the University produced a set of three course manuals; 400 sets were distributed to hospitals which teach radiologic technologists, as well as to State and local health departments. The manuals were also sold by GPO.

In 1976, a quantity of surplus manuals was received from GPO; these sets were distributed to all schools of radiologic technology and radiation therapy.

In accordance with the contract, the manuals have been revised by the University and are currently being reviewed by the Bureau. The Bureau plans to make the second edition available through GPO in the fall of 1977.

Radiologic Administrator Training

The Bureau supported a project at the University of Cincinnati to develop and conduct a prototype training program in radiologic administration; graduates of the 12-month program receive a Master of Science degree. Bureau support ended in 1974, but the program has continued. Thirty individuals have been graduated and are currently employed as follows: 21 radiologic administrators; 6 directors of RT training programs; and 3 technical sales representatives.

Programed Instruction for Practicing Physicians

Although the Radiological Health Sciences Learning Laboratory described above shows great promise in teaching radiation protection principles to medical students, it is also vital that this message be communicated to physicians already in practice. To help fill this need the Bureau developed a two-part programed-instruction series entitled "How To Protect Patient and Physician During X-Ray Examinations." Presented in self-teaching format, the program discusses the biological consequences of x-ray exposure, the criteria to be used in selecting patients for x-ray examinations, techniques to be employed during the conduct of the examination which spare patients unnecessary radiation exposure, and protection of the operator against radiation during the examination.

Through a cooperative arrangement with the American Academy of General Practice, this program was published in the journal *American Family Physician* in January and February of 1970, thus reaching 112,000 practicing physicians in the United States. Physicians who completed the program were given the opportunity to take a test covering the material taught in the program, and on this basis received credit for continuing education from the Academy. Since publication of the material, the Bureau has provided individual copies to a number of physicians, hospitals, and teaching institutions which requested them.

Publications

Another means by which the Bureau communicates its message to health practitioners is the production and large-scale distribution of brief, practical booklets on timely radiological health topics. Some of these booklets are described below.

"X-ray Examinations . . . A Guide to Good Practice"—This is a publication designed to improve the judgment and technical procedures of physicians and other health practitioners who use X-ray equipment, or order X-ray examinations to be performed on their patients, although they are not specially trained in radiology. Almost one-half million copies have been distributed through the cooperation of national professional and technical organizations, and 12,000 have been sold by GPO. The Pan American Health Organization translated the booklet into Spanish and has printed 10,000 copies for distribution.

"Fast Film Exposure and Processing in Dental Radiography"—Designed for dentists, this booklet shows how to successfully use and process fast film, thereby effecting a significant reduction in exposure with no loss of diagnostic quality. Seventy thousand copies were distributed.

"Radiation Protection for Podiatrist and Patient"—This pamphlet provides practical information to enable podiatrists to minimize exposure to themselves, patients, and office personnel. Twenty thousand copies were distributed and 1,600 have been sold by GPO.

"Radium and the Physician"—This publication provides physicians with basic information concerning radium and its hazards. Facts about radium are presented, including the extent of its radiotoxicity, the likelihood of source leakage, and shielding requirements. Typical problems in handling and storage are also presented, together with means of minimizing such problems. Fifteen thousand copies were distributed and 1,500 have been sold by GPO.

In addition to the above general-interest booklets for large-scale distribution, the Bureau publishes technical reports on more specialized topics. About 4,000 copies of these reports are usually printed and distributed to State and local radiological health program personel, Bureau technical staff and advisory committee members, university radiation safety officers, libraries and information services, industry, hospitals, laboratories, schools, the press and other interested individuals.

Training Package Series for Radiologic Technologists

The Bureau has developed a multi-media package training program for radiologic technologists, entitled *Radiation Protection During Medical X-Ray Examinations*. This program was designed in modular form so that new parts could be added to the series to explain new radiation protection techniques which might be developed in response to findings of Bureau surveillance activities. Five modules have now been developed:

Part I. Principles of X-Ray Protection.
Part II. Checking the Accuracy of the Light Beam in a Collimator.
Part III. Calculating the Beam Size from a Cone.
Part IV. Biological Effects of X-Rays.
Part V. Gonad Shielding in Diagnostic Radiology.

These packages may be purchased from the National Audiovisual Center, GSA. To date, about 1,500 individual packages have been sold. Also 125 copies of each package are available for free loan.

Opinion questionnaires are included in the packages; completed questionnaires indicate that approximately 20 persons view each package yearly. Considering overlapping data, it is estimated that a minimum of 10,000–12,000 individuals view this radiation protection material yearly.

Self-Assessment Continuing Education

Although the Bureau of Radiological Health has developed many educational programs to assist students in academic institutions, it also recognizes that a great need exists for continuing education. Consequently, the Bureau has developed a means to bring continuing education to the approximately 130,000 practicing x-ray technologists in a systematic way, and to provide for updating the system in the future as needed.

Under a Bureau contract, the American Society of Radiologic Technologists (ASRT) has produced a series of self-assessment tests (each covering a particular subject matter category) for practicing x-ray technologists. Each test is designed to help identify areas in which individuals should pursue education or training. A series of bibliographies of educational material is keyed to the test results.

The system has been pilot-tested on 200 x-ray technologists in the private sector. Also, the Veterans Administration has administered the self-assessment tests to about 1,500 x-ray technologists in its medical care system in order to determine continuing education needs. The ASRT is now attempting to determine the best means to make the continuing education system available on a nationwide basis. It is estimated that the system could potentially be used by about 20,000 technologists annually.

Syllabus for Schools of Radiologic Technology

As documented in a number of studies, the radiation protection performance of x-ray technologists credentialed through the present voluntary registration system is far from adequate. Part of the fault lies with the weak system of education, in which curriculum content varies considerably among schools and the qualifications of faculty members are not assured.

Most radiologic technologists in the United States are trained in the approximately 1,200 American Medical Association-approved x-ray technology training programs, which have an enrollment capacity of 20,000 students. There are also 250 students enrolled in the 20 programs accredited by the American Registry of Clinical Radiography Technologists.

In order to improve radiation protection curricula in schools of x-ray technology, the Bureau of Radiological Health has developed a syllabus on radiation protection, based on behavioral objectives, to provide guidance to instructors. This syllabus has recently been published as part of the American Society of Radiologic Technologists' Syllabus, used in all the AMA-approved technology training programs. Periodic review and updating will provide an opportunity for the Bureau to include the most recent radiation protection guidance.

Training Package on X-Ray Protection for Podiatrists

Over the past few years, State and local radiation control agencies have received a number of requests from podiatric groups for training workshops on protecting patients against needless radiation exposure during podiatric x-ray examinations. In order to encourage and facilitate these activities, the Bureau prepared a training kit to assist State and local radiation control personnel in teaching protective practices to podiatrists. The kits, consisting of a suggested training schedule, detailed lecture outlines, handout materials for attendees and suggested reading for the instructor, were distributed to the FDA regional offices, and thus made available to State and local programs.

Dental Training Packages

The radiation exposure to patients from dental x-ray examinations could be drastically reduced by adherence to such straightforward radiation protection principles as proper beam-limiting cones and standardized darkroom procedures. The Bureau is currently conducting several training efforts directed at teaching these principles to dental auxiliaries, dental students, dentists, and individuals involved in the education of dentists and dental auxiliaries.

An instructional program has been developed which presents an 8-hour curriculum for dental auxiliaries in the safe operation of x-ray equipment, protection of the patient, beam limitation, and other radiation protection principles. The package includes "home-study" material which the auxiliary can study on his own time without the aid of a professional. The package was originally developed for the Maryland State Dental Association and is currently being used on a review basis.

A substantial portion of the data obtained from the Bureau's nation-wide surveys of x-ray practice in 1964 and 1970 deals with the use of radiation in dentistry. The Bureau has analyzed from these two surveys specific trends in dental x-ray practice which indicate both the effectiveness of existing radiation reduction programs and the relationship of particular radiation protection practices to exposure reduction. This information will be made available to dentists through publication in a dental journal. By maintaining an awareness of the importance of radiation protection principles in the dental office, dentists should be encouraged to conduct their own quality control programs and improve their radiation protection practices.

The Bureau, through a contract with the University of Alabama, has developed a training program for teachers of dental radiology in auxiliary training schools. This contract called for the development of a pilot course for teachers and the completion of a Teacher's Manual, which has been published and distributed by the Bureau. The Bureau's continuing role in this project is to encourage nationwide presentation of similar courses and incorporation of the Teacher's Manual into the curricula of schools for dental auxiliaries. The first regional presentation of this course was in June 1974.

The importance of dental darkroom practices in reducing unnecessary radiation exposure in dentistry has long been recognized. Through the development, distribution, and sale of a Slide-Tape Lecture Series on Dental Darkroom Procedures, the Bureau is actively working to improve darkroom practices. This program is a series of three self-contained 20-minute slide/tape presentations on dental darkroom requirements, processing procedures, and film processing failures with related corrective measures. This package provides dental educators with material which can be used in schools for dental auxiliaries, in dental schools and in continuing education programs for licensed practitioners.

Dental Table Clinics

A dental demonstration, or table clinic, is presented by Bureau personnel each year at the Chicago Mid-Winter Dental Convention, which is a major national dental meeting. Among the Bureau-developed devices shown at these table clinics has been a rapid dental x-ray film processor for selected procedures, which can be easily constructed by a dentist for about $15. It employs an aquarium heater to maintain a processing temperature around 92° F, enabling films to be procceased in less than 1 minute. Use of this setup in procedures which require quickly-available films saves at least 5 minutes' processing time per film and avoids the overexposure of patient and film which is sometimes employed in such circumstances to permit quick processing at normal temperatures.

Another Bureau table clinic presented a simple means for dentists to convert their x-ray machines from 2.75-inch to 2-inch collimation at negligible cost. This produces sharper radiographs while reducing the exposure area at the cone tip by 50 percent, thus also significantly reducing patient dose.

Nashville Demonstration Project

The Bureau has completed a pilot project to examine present x-ray practices in private dental offices and to test the effectiveness of an educational program to motivate dentists toward protective practices.

In the initial phase of the pilot project, dental students (through contract with Vanderbilt University) and BRH radiological health personnel surveyed 72 dental facilities in the Nashville, Tennessee, area to determine existing x-ray practices and machine characteristics. The radiological health specialists then revisited the dental facilities, discussed the survey findings, and made specific recommendations to the dentists for improving their radiologic practices. A follow-up survey of the same facilities was conducted in the summer of 1973 to determine the effectiveness of this type of educational program in reducing unnecessary radiation exposure and improving the practice of dental radiology. The results of this pilot project were published and distributed by the Bureau.

Educational Program on Mass Chest X-Rays

Mass chest radiography of the general population for the purpose of detecting tuberculosis and other cardiopulmonary diseases has been a standard practice of public and private health agencies throughout the United States. Recent studies have shown that the number of new cases of active cardiopulmonary disease discovered through mass screening programs is so low that these programs should be discontinued among the general population and employed only in high-incidence areas or for special population groups who may be particularly susceptible to lung disease. This low yield of new cases represents a very large population exposure to x rays, since the number of x-rays taken annually for this purpose has been in the tens of millions.

The problem is compounded by the fact that the photofluorographic machines which are commonly used in mass chest screening can expose each individual to up to 10 times more radiation than a conventional chest x ray. Conversely, the tuberculin skin test is more accurate than the x-ray film in indicating the presence of tuberculosis, and requires no radiation exposure. Only those few individuals whose tuberculin test is positive are x rayed to determine whether the tuberculosis is active.

For all these reasons, the Bureau of Radiological Health, the American College of Radiology, and the American College of Chest Physicians prepared a joint statement in early 1972, which made two principal recommendations:

"1. The community chest survey among the general population should not be used as a screening procedure for tuberculosis, other pulmonary disorders and heart disease.

"2. When chest x-ray screening programs are justified for selected population groups, the full size x-ray film, rather than the miniature film used in photofluorographic equipment is preferred."

The Bureau is currently developing guidelines on use of the routine chest radiograph by practitioners of the healing arts and others (e.g., employers, hospitals, government agencies). The intent is to ensure maximum utility for the examination and eliminate unproductive radiation exposure to the general population.

E. EDUCATING CONSUMERS OF RADIATION SERVICES

To complement its efforts to educate health care personnel in safe radiation practices, the Bureau has undertaken a program to teach patients how they can help to minimize unnecessary medical radiation exposure to themselves and their families. An informed patient can ask and understand why a given radiologic procedure is needed, can alert the physician to previous x-ray studies or to early pregnancy, and can request that protective measures (such as gonad shielding) be used when appropriate. The initial program in this area includes a series of articles in the monthly *FDA Consumer* with distribution of reprints to FDA Consumer Affairs Officers and other interested consumer groups for public dissemination. A series of slide/tape packages which consumer groups can use to explain various radiological health issues is under development. Consumer posters and pamphlets on such topics as x-ray use during pregnancy are being prepared for display in radiologists' offices, general medical facilities, and various public facilities.

F. ESTABLISHING STANDARDS FOR USER QUALIFICATIONS

Model Legislation for Users of Ionizing Radiation in the Healing Arts

To help eliminate the broad disparities among State licensure requirements, the Bureau of Radiological Health in 1970 published a model law, developed in collaboration with States and professional organizations. The chief aim of the Model Legislation is to encourage the establishment of a regulatory framework for licensure of users of ionizing radiation, including practitioners, which is consistent among all States. It is anticipated that reductions in population exposure to radiation would then be effected through improvement in the qualifications of professional and technical radiologic personnel.

Proficiency Test for X-Ray Technologists

A significant portion of today's unnecessary x-ray exposure of the population is caused by x-ray machine operators who lack sufficient motivation, knowledge, and skill to adequately protect the patient. Among the approximately 130,000 nonpractitioners presently operating x-ray machines in the United States, roughly half are noncredentialed, i.e., are neither licensed by a State nor registered by a professional organization. (Current registration and licensure practices require applicants to complete an approved training program and pass an examination.)

In an effort to upgrade the competence of nonregistered, nonlicensed operators, the Educational Testing Service is developing a comprehensive proficiency test under a contract from the Health Resources Administration. The Bureau has assisted in this effort by providing consultation and test materials in the area of radiation protection. The test is being developed under the requirement of Section 241 of Public Law 92–603 (the Social Security Amendments of 1972) that the Secretary of HEW develop proficiency tests for x-ray machine operators who are not qualified through the normal credentialing channels and who work in institutions seeking eligibility for reimbursement under Titles XVIII and XIX of the PHS Act (Medicare and Medicaid).

State Licensure of X-Ray Technologists

About 27,000 licensed technologists currently practice in New York, California, New Jersey and Puerto Rico, the only U.S. jurisdictions with operational licensure programs. In addition, Minnesota, Vermont, Hawaii, Oregon, Georgia, Montana, Delaware, Michigan, and Kentucky currently have authority to initiate standards for education, training, and licensure of x-ray technologists.

The four present licensure programs are not identical. California is the only State to require licensing, not only of technologists, but also of physicians who operate or supervise the operation of x-ray equipment. California also provides for "limited categories" of technologist licenses, i.e., some individuals are licensed to perform only certain specified x-ray procedures. All the State programs require approval of technology schools, although their effectiveness in enforcing this and other provisions of the law may vary. The differences among State licensure regulations have created a number of problems, such as possible shortages of qualified personnel in rural areas, difficulties with reciprocity between States, and lack of uniform criteria for accreditation of schools.

The Bureau of Radiological Health has assisted in establishing a Task Force of State Credentialing Programs, under the sponsorship of the National Conference of Radiation Control Program Directors. The functions of this Task Force are: (a) to analyze problems associated with licensure program administration; (b) to assess the effectiveness of such programs; (c) to provide uniformity among licensing States; and (d) to encourage more flexible and innovative State credentialing systems.

U.S. Civil Service Commission Employment Standards

Several Federal agencies are direct employers of x-ray technologists. Government facilities, including military installations, employ approximately 8,000 of these individuals. Although Federal health facilities should assume a leadership role in providing the highest quality of care, the qualifications of Federal x-ray technologists are often poor. This is primarily due to antiquated Civil Service Commission classification and qualification standards for this field. Appropriate changes in the standards would help assure quality radiological care for Federal beneficiaries and might also stimulate the private sector to follow the Federal model.

Bureau of Radiological Health staff were instrumental in initiating a Task Force on Medical Radiology Technicians to develop new Civil Service classification and qualification standards which would reflect current trends in radiologic practice. The recommended standards have been submitted to the U.S. Civil Service Commission for their consideration.

Revision of Medicare Standards for Radiology

Several HEW components have direct impact on the qualifications of x-ray technologists practicing in the United States. For example, the Division of Provider Standards and Certification, Bureau of Quality Assurance, HSA, is responsible for developing criteria for participation of facilities under the Medicare program. Approximately 50 percent of the technologist workforce is employed in facilities participating in the Federal Health Insurance for the Aged Program. If national health insurance legislation is implemented, the effect of such criteria would be even more far-reaching than at present.

The Bureau of Radiological Health has proposed criteria pertaining to x-ray technologist qualifications that can be used in upgrading and maintaining radiology standards for Medicare facilities. These criteria have been provided to the Bureau of Quality Assurance.

G. UPGRADING STATE AND LOCAL RADIATION CONTROL PROGRAMS

Training Seminars

In order to upgrade the competence of State and local radiation control personnel to carry out their radiation protection responsibilities, the Bureau conducts, and helps States and Regions conduct, seminars and workshops in various aspects of radiological health. Some of the seminars are aimed at teaching new personnel the basic principles of radiation science and protection; others concentrate on the skills and techniques necessary for surveying and evaluating medical x-ray equipment in hospitals and offices; still others deal with the inspection of consumer products such as microwave ovens.

This program has been active since the mid-1960's, and has been largely responsible for establishing and maintaining the pool of manpower trained in radiation protection among the State and local radiation control agencies. However, because of increased emphasis in recent years on educating users of medical radiation, and because of staff and budget restrictions, the number of these seminars presented by the Bureau has been sharply curtailed. At present the Bureau provides direct training to about 200 individuals annually, through approximately 10 seminars presented jointly with host States. This training is designed to meet the needs determined by the Regional Training Committees.

Regional Training Committees

The difficulty of State and local radiation control agencies in meeting the training needs of their personnel after the curtailment of Bureau seminars and workshops has been compounded by the ending of the Environmental Protection Agency's radiological health training program. In an attempt to increase the effectiveness of what remains of this Bureau program within existing budgetary and manpower limitations, EPA, the Bureau, and the States have cooperated since 1973 in establishing Regional Training Committees (RTC's).

The functions of the RTC's are: to allow neighboring States to jointly ascertain their training needs in advance; to investigate local resources (universities, hospitals, etc.) which might help to fill these needs; and to plan for cooperative training activities, with the assistance of the two Federal agencies whenever possible. Thus far, RTC's have been established in nine regions, and are being coordinated through the FDA and EPA regional offices. The Bureau's participation in training of State and local radiation control personnel since the establishment of the RTC's has related to needs dictated by the Bureau mission. Examples are training related to routine surveys of new x-ray equipment (e.g. Advanced X-Ray Survey Workshops) and training related to new Bureau programs (e.g. Nationwide Evaluation of X-Ray Trends, Dental Exposure Nationwide Trends, Breast Exposure Nationwide Trends). These programs are described elsewhere in this document.

An additional function of the RTC's is to encourage and facilitate presentation of continuing education programs for radiation users, such as x-ray technologists and podiatrists, by State and local personnel. Training Methodology Workshops are presented to States or Regions by the Bureau on request, to improve the training techniques of their personnel. The Training Resources Center described below and the various self-contained training packages developed by the Bureau should also help considerably in this effort.

Training Resources Center

With support from the Bureau, the State radiological health agencies are gradually beginning to involve themselves in the continuing education of radiation users. One of the difficulties the States are encountering in trying to establish their own training programs is a lack of training materials. In FY 72 the Bureau began a program of identifying and consolidating training materials which were to be made available primarily to State radiation control programs for use in the development of their own training activities. This culminated in the establishment and operation of a Training Resources Center, a clearinghouse for training materials relating to radiation protection, radiation control, and good radiologic practice. The Center, as it now exists, contains training manual segments, slides, videotapes, and other materials, many of which were produced for training courses previously presented by the Bureau. The Bureau has produced a bulletin listing these materials and has distributed it to Federal, State, and local radiological health personnel. Comments to date have indicated widespread support for this program.

Radiological Health Handbook

Part of the Bureau's function in dealing with users of radiation is to improve and maintain the competence of radiation control personnel on the Federal, State, and local levels. As a part of this goal, the Bureau has compiled and developed a compendium of practical data useful to individuals responsible for radiation protection in both the medical and industrial environments. This document, called the *Radiological Health Handbook*, had been issued by the Bureau through the Government Printing Office since the early 1050's. In 1970, the handbook was substantially revised, and a new edition was produced. To date, more than 4,000 copies of the new edition have been distributed by the Bureau and 24,000 have been sold by GPO.

Training Assistance to Other Federal Agencies

In addition to the training activities directed toward State and local personnel described above, the Bureau also cooperates with other Federal agencies in presenting training in radiological health. Examples of this cooperation include:

A course in radiopharmaceuticals for drug inspectors, presented by the EDRO and BRH components of FDA.

A course in the handling of radioactive materials for laboratory personnel of FDA's Bureau of Foods.

A course in x-ray survey techniques for Indian Health Service inspectors.

A course in the reduction of exposure to patient and operator for x-ray personnel in the Bureau of Prisons.

Liaison is maintained with the U.S. Army, the Veterans Administration, the Health Services Administration, and other agencies in areas of mutual interest regarding training in the radiological health sciences.

Evaluation of State Radiation Control Efforts

The Bureau has contracted to have the University of Iowa State Hygienic Laboratory in Iowa City perform NEXT (Nationwide Evaluation of X-Ray Trends) surveys in a representative sample of Iowa's x-ray facilities. As explained in Section II.A, NEXT surveys are a standardized data collection technique for field measurements of x-ray machine output for various radiographic procedures in diagnostic x-ray facilities throughout the country. The measurements, from which exposure and organ doses to a "standard patient" are calculated, are performed by participating radiological health agencies to measure the effectiveness of their own radiation control programs, while the Bureau uses the data as a basis for assigning program priorities.

Iowa is one of three States with no formal radiological health program. The contract, in addition to enabling NEXT surveys to be performed in Iowa facilities for the first time, will provide the State of Iowa with information that can be used to evaluate the need for establishing an x-ray protection program within its State Health Department.

Upon completion of the survey, a comparative analysis of existing NEXT data and the data obtained through the Bureau contract will be used to determine the need for medical radiation control programs in the three States which do not already have them, and possibly to develop recommendations concerning existing State programs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., November 11, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Service, and Transportation, U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in further reply to your letter of September 27, 1977, in which you requested supplemental information on our radiation control activities. Enclosed are the responses to all of the questions raised in your letter. We trust that this information will help you and your staff in completing the hearing record and finalizing the Committee report.

We appreciated the opportunity to appear before your Committee at the June hearing. If we can be of further assistance, please let us know.

Sincerely yours,

SHERWIN GARDNER, *Deputy Commissioner.*

Enclosure.

Question 1. Many witnesses before the Committee expressed great concern with respect to overuse of radiation in medicine for either diagnosis or for therapy. Dr. Shiff stated at page 21 of the transcript, "There have been changes in usage, but the overall amount of radiation that is being given for clinical reasons is on the increase." Does the FDA agree or disagree with this statement? Please provide references in support of your opinion.

Answer. FDA agrees that actual exposure of the population may be on the increase simply because a greater number of medical radiologic procedures are being performed now than previously. Between 1964 and 1970, the annual number of examinations in the United States had increased 24 percent, from 173 million to 212 million. An extrapolation of this data shows that approximately 270 million examinations will be performed in 1977 (FDA publication, *Population Exposure to X-Rays—1970,* November 1973).

The recent introduction and proliferation of the x-ray computed tomography (CT) scanners has also contributed to population exposure. Already, approximately 400 CT scanners are being used on about 100,000 patients per year, and it has been projected that seven times this number of patients will be exposed. However, it should be noted that several authors have documented a decrease in other more hazardous procedures such a pneumoencephalography, because of substitute CT procedures.

Indirect evidence also supports the argument that the number of x-ray procedures per unit of population is increasing. For example, the 1972 Bureau of the Census Report of Manufacturers documented a rise in sales of medical x-ray film from 440 million square feet in 1967, to 722 million square feet in 1972. During the same period, the U.S. population increased from 199 million to 209 million persons. Therefore, on a per person basis, film sales increased from 2.2 square feet per person to 3.5 square feet per person. A 1976 Wolfman Report on the photographic industry in the United States similarly showed that 355 million sheets of medical x-ray film were consumed in 1966 compared to 910 million in 1976. On a per person basis, that amounts to an increase of 1.8 sheets per person to 4 sheets per person. Coinciding with the increase in film consumption is an increase in the number of U.S. radiologists. In 1963, there were 7,324 while in 1975 this number had risen to 14,505 (*American Journal of Roentgenology,* pg. 576, October 1976).

Question 2. "Please explain the data base and radiation protection philosophy employed by your agency in formulating the microwave oven standard. How does the FDA determine if the ovens in use in the home comply with that portion of the standard applicable to ovens for the life of the product? How can a consumer determine if his or her oven is emitting radiation in excess of FDA's standard?"

Answer. A considerable body of evidence demonstrated the potential biological hazard of electromagnetic radiation having a frequency of 30–300,000 MHz. This range includes frequencies used in microwave ovens. A number of biological effects have been observed following microwave exposure, primarily in studies with animals. These include:

(1) Cataract induction;
(2) Testicular pathology;
(3) Central nervous system effects;
(4) Mitotic and chromosomal abnormalities in cells;
(5) Alteration in electrophoretic, immunologic and enzymatic activity of proteins;
(6) Interference with cellular differentiation in the absence of effect on cellular proliferation;
(7) Decreased incorporation of labeled amino acid into liver and testis; and
(8) Lethality in various animal species.

There was little question, from the foregoing, of the potential hazard of microwaves. There was a question, however, about the emission level that provides adequate public health protection. The value proposed for an emission standard was 1 mW/cm^2 measured at 5 cm. This value is a factor of 10 below the existing recommended maximum permissible exposure of 10 mW/cm^2 adopted by the American National Standards Institute. A factor of 10 below 10 mW/cm^2 for safety was not overly conservative for the following reasons:

(1) We were dealing with an uncontrolled population, and the uncontrolled use of a potentially dangerous source of electromagnetic radiation. For example, food service establishments including restaurants, hospitals, etc., employ operators of microwave ovens that could be exposed repeatedly for many hours per day to microwaves that may emanate from such devices. Further, exposures in such establishments, as well as in homes, could occur under conditions of high ambient temperature and high humidity.

(2) No control was or is possible over the state of health of users. It should be noted that research with animals has employed uniformly healthy subjects.

(3) The possibility of cumulative effects had been raised by research, and would not be ignored. Since the potential for exposure of large populations of very young people exists, this raised the question of effects of intermittent repeated exposure over the lifetime of an individual.

(4) Uncertainty existed over the work of scientists in the U.S.S.R. which could not be easily dismissed. It should be noted that interaction between low levels of microwaves and the nervous system has been established in this country by the work of Frey, who demonstrated evoked brain stem responses with pulsed microwaves at intensities as low as 30 $\mu W/cm^2$.

(5) Microwaves from ovens were only one source of electromagnetic radiation to which human populations were exposed. Other sources of electromagnetic radiation existed both in the nonionizing and ionizing frequencies, and the possible biological interactions of multiple electromagnetic radiation insults had not been fully investigated. Further, exposure to multiple environmental insults incuding bacterial, viral, and chemical agents, and the complicated interactions of these agents with radiation, including possible synergistic effects, had not been adequately evaluated.

All of these factors suggested that most serious consideration be given to a maximum level of 1 mW/cm^2 for the protection of public health and safety.

This original biological basis for the FDA Microwave Oven Performance Standard obviously reported several research areas in which inadequate data were available to fully specify the biological effects of microwave radiation. A review of recent information relevant to those research areas has documented adequate reasons for continued concern with the potential hazards associated with microwave radiation.

The areas of most concern included the uncertainty regarding the quality of East European research, the effects of repetitive and/or long-term exposures, and the possibility of interaction between microwave radiation and drugs or environmental factors.

A majority of the research reporting biological effects of low-level microwave radiation (less than 20 mW/cm^2) emanates from East Europe. The credibility of these findings is therefore critical in evaluating the hazards of microwave radiation. The lack of dosimetric quantification in some of the early Soviet research has been noted by Russian scientists. Also, precise dosimetric quantification is difficult to achieve in epidemiology which comprises a small but significant portion of the East European research.

The absence of detailed descriptions of experimental procedures in the Soviet literature has also been noted. It is the Bureau's opinion that this criticism is more closely related to the information cited in the papers, which are most readily available in translation, are extensive reviews of original research. Typically, such reviews do not include procedural detail. Those original research papers, which are available in translation, present as much detail as comparable Western research publications.

East European research also has gained much stature in the view of many Western observers as a result of recent multi-national conferences and face-to-face meetings between Eastern and Western scientists. The increase in contact between Eastern and Western scientists has helped to mitigate some of the uncertainty regarding the effects of repeated exposure to microwave radiation. Most of the biological effects of low-level microwave radiation occur following chronic or repeated exposure. While few direct comparisons have been made, the data seem to indicate that biological endpoints unaffected by a single exposure to relatively high-energy flux densities may be affected by repeated exposure to lower energy levels.

Uncertainty still exists regarding the influence of exogenous agents upon the observed biological effects of microwave radiation. Very few studies have been reported, but those which have indicate an interaction between microwave radiation and psychoactive drugs, and between microwave and x irradiation. Similarly, almost no research has been reported regarding the relation between the health status of an organism and the effect of microwave radiation upon that organism. From a public health agency viewpoint, there is every reason to continue to believe the position taken in promulgating the microwave oven standard to be correct.

The principal thrust of FDA's enforcement programs is aimed at ensuring that ovens will comply with the standard throughout their lifetime. We review the ovens' design and the manufacturers' quality control procedures through review of a manufacturer's reports and factory inspections. Manufacturers perform endurance tests of all models and FDA has its own in-house endurance test program. These test results indicate that most modern ovens do not deteriorate with age where leakage is concerned. Manufacturers are required to test every oven they produce for compliance with all safety aspects of the standard. They are held to a leakage level 5 times lower than that allowed in use (for the life of the product).

We also test ovens during inspections and have an extensive intra-Agency field test program and cooperative programs with many States which account for about 4,000 ovens per year. Our test data is in a computer bank and we review this for any trends which would indicate microwave leakage with time or as a result of use. In 1978, we will begin a program of test stratification whereby we will concentrate our field efforts to provide valid statistical samples of those ovens deemed most likely to present compliance problems. If the oven is certified, i.e., produced after the standard went into effect and particularly if it is less than 2 or 3 years old, the consumer need not be concerned about leakage radiation from the door seal, latches and hinges which have not been damaged in any way. If damage is suspected, the consumer can call the State or local radiological health office where they exist or the nearest FDA resident district or regional office and arrange to have their oven tested for compliance with the standard.

Attached: DHEW Publication No. (FDA) 77–8037, "Procedures for Field Testing Microwave Ovens."

Question 3. With respect to baggage x-ray inspection units in use in the nation's airports, which Federal agency has the responsibility for determining that the operators and the public are not exposed to unnecessary radiation? Are the statutory authorities clear in this respect? In fact, is any agency enforcing either an emission or exposure standard?

Answer. The Food and Drug Administration, under the authority conferred by P.L. 90–602, The Radiation Control and Safety Act of 1968, is the Federal agency responsible for ensuring that the general public is protected from sources of unnecessary radiation exposure. This includes x-ray baggage inspection systems which today are widely used for purposes of surveillance. The FDA's Bureau of Radiological Health promulgated a performance standard for these devices which became effective on April 25, 1974. The standard provides for engineering designs that limit the amount of radiation to that which is needed for the proper operation of the unit and restrict the accessibility to the radiation source by both operators and airline passengers, thereby avoiding accidental exposure.

It should be emphasized that the FDA standard focuses on the performance of the equipment by placing an emission ceiling of 0.5 milliroentgens per hour at any point 5 centimeters (or about 2 inches) from the external surface of the device. Biannual inspections of these units for compliance with this emission standard are required by the Federal Aviation Administration (FAA). No provision in the FDA standard requires monitoring of persons who operate such units, nor does it mandate periodic review of occupational exposures or apprising employees of such exposures. The FAA, however, requires that either individual airlines or security groups under contract with that Agency provide monitoring of occupational personnel. OSHA is responsible for maintaining personnel exposure records. The basis for the FDA standard is for operational exposures to be maintained at a level which poses no health hazard to either passengers or occupational personnel.

Should a situation arise in which a unit is suspected of emitting radiation in excess of the limits imposed by the Agency's performance standard, FDA, FAA, and OSHA are empowered to conduct on-site inspections to determine the compliance status of that particular unit. The authority with respect to the regulation of the emissions from x-ray baggage systems is clearly vested with FDA. Although potential for duplication does exist, efforts thus far have been well coördinated and effectively maintained so as to avoid duplicative activities.

Question 4. "During the hearings, Mr. Gardner stated: 'Acute exposure to ultrasound has been shown to cause birth defects in rodents and to initiate blood clotting in the region of application', and 'Acute exposure to microwaves sufficient in intensity can cause cataracts; some evidence now points to the possibility of cumulative damage from lower levels of exposure.' (transcript, page 35). Please provide further documentation for these statements."

Answer. Research over several years led to the publication of data on blood platelet aggregation after exposure to a therapeutic ultrasound device. Attached are copies of these reports from the working files of our staff.[1]

The question of birth defects in rodents exposed to ultrasound is addressed in research publications by researchers on our staff and in Japan. The positive results are noted in the copies attached. In addition to these reports, members of our research staff have commented in a letter to the editor of *Lancet*, on the biochemical, electrical, and behavioral effects produced by exposure of the central nervous system to ultrasound. This is also attached for your information.[2]

The Agency's own research program has addressed the question of microwave cataracts. The results support the statements made above and have been published as the data became available. Two reviews of the large volume of available data are attched as specific documentation of the potential hazard to the eye from exposure to microwave radiation.[3]

Question 5. Please clarify whether or not the FDA inspects pre-1974 medical x-ray equipment. During the hearing, it was stated that FDA does not inspect any 'old' equipment. However, in the questions received by the Committee prior to the hearing, Commissioner Kennedy stated that about 8 percent of the equipment inspected was old equipment.

Answer. In the interchange with Senator Ford (page 39 of the transcript), Mr. Villforth remarked, "We don't normally inspect old equipment. We encourage the States, who have specific responsibility under State regulations to inspect all such machines." The FDA's day-to-day operations do not routinely find us inspecting pre-1974 machines. However, as part of our contractual agreements with States (twenty-two as of October, 1977), we have evaluated the performance of x-ray systems not subject to Federal standards for purposes of comparing noncompliance of certified versus non-certified units and the resultant unnecessary radiation exposure. Since the inception of these State contracts in 1974, nearly 8,500 diagnostic x-ray systems have been evaluated, either by the States themselves or by members of FDA's field force. Of this number, approximately 500 have been machines that were totally non-certified and about 1300 of these were units having certified and non-certified components. These contracts also permit us to identify equipment for which defect action, applicable to x-ray systems manufactured after 1968 and prior to the 1974 Federal standard, could be instituted pursuant to Part 1003.2, 21 CFR Subchapter J.

We view the States as a vital extension of our efforts to control, and where practicable, reduce unnecessary patient exposure to radiation. This Federal/State partnership is exemplified by the development and implementation of the Suggested State Regulations for Control of Radiation, which serves as a template for State requirements and inspection protocols. In addition, as mentioned above, the FDA works with 22 States through the contract process to inspect and gather data on diagnostic x-ray equipment.

Question 6. During the hearing, Mr. Villforth stated that virtually all of the States have some type of surveillance and inspection program modeled after the suggested state regulations. Just how many States actually do inspect old equipment on a regular basis?

Answer. Virtually all of the 50 States have radiation control programs authorized by State legislation. Nearly all have specific radiation control regulations, fashioned chiefly after the Suggested State Regulations for Control of Radiation. These model regulations serve as a guide to foster uniformity among requirements and procedures adopted and implemented by the States, and to insure that State regulations are compatible with those issued by the various Federal agencies. Such regulations serve as a working basis for the States in their inspection of medical and dental x-ray equipment manufactured prior to the effective date of FDA's Federal performance standard (August 1974).

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[1] Williams, Sykes, and O'Brien, "Ultrasonic Exposure Modifies Platelet Morphology and Function *in vitro.*" *Ultrasound in Med. & Biol.*, vol. 2, pp. 311–317, Pergamon Press, 1976.

Williams, "Release of Serotonin from Human Platelets by Acoustic Microstreaming," *J. Acoust. Soc. Am.*, vol. 56, No. 5, November 1974.

Shoji, Momma, Shimizu, Matsuda, "An Experimental Study on the Effect of Low-Intensity Ultrasound on Developing Mouse Embryos," *Journal of the Faculty of Science, Hokkaido University*, Series VI, Zoology, vol. 18, No. 1. 51–56, October 1971.

O'Brien, "Ultrasonically Induced Fetal Weight Reduction in Mice," Curto, "Early Post-partum Mortality Following Ultrasound Radiation," *Ultra Sound in Medicine: Proceedings of the 20th Annual Meeting of the American Institute of Ultrasound in Medicine,* New York, 1976.

[2] See *The Lancet,* issues of May 7, 1977 and June 4, 1977.

[3] Carpenter, Ferri, Hagan. "Assessing Microwaves as a Hazard to the Eye—Progress and Problems,' *Biological Effects and Health Hazards of Microwave Radiation: Proceedings of an Int. Symposium*, Warsaw. Oct. 15–18. 1973. pp. 178–185.

Carpenter and Van Ummersen, "The Action of Microwave Power on the Eye," *Journal of Microwave Power,* vol. 3, No. 1, pp. 3–19 (1968).

Attached for further reference is an FDA publication entitled, *Report of State and Local Radiological Health Programs—Fiscal Year 1976.*[4] This document provides a nationwide perspective on the resource levels and activities in States in the area of radiation control. Note in particular pp. 8–19, which summarize data received from States on FY '76 inspection coverage of medical and dental x-ray equipment.

Question 7. During the hearing you said that the inspection of old machines is the state's responsibility. You further said that the FDA does not have the right of entry into the physician's office for that purpose. In view of the fact that everyone agrees that the old, unmonitored x-ray equipment is a large part of the problem, why has the Bureau of Radiological Health not recommended to Congress legislation authorizing it to inspect old medical x-ray equipment?

Answer. The Federal diagnostic x-ray performance standard regulates the manufacturers of x-ray equipment. The various State radiological health programs have traditionally regulated the use of such systems. The two programs are complementary, and provide the necessary coverage for equipment. The "old," non-certified equipment is *not* "unmonitored." Rather, it is routinely evaluated by the States, usually done in a priority fashion, focusing on facilities where the greater number of machines exists and more x-ray procedures performed. Several of FDA's defect actions have been initiated in response to information received from States.

Also, the percentage of non-certified x-ray equipment in use today is steadily declining. Data reveal that there is a replacement rate of about 10 percent per year, and that these replacements are x-ray systems subject to Federal standards. Therefore, the FDA believes that sufficient authority presently exists to detect and correct defective non-certified x-ray machines, and that current reliance on State radiation control programs to identify x-ray equipment performance problems should continue.

Question 8. Please explain in further detail the FDA's compliance testing program under contract with 18 states. Is the Committee to infer that the medical x-ray equipment assembled in the other 32 states has not been tested by anyone since the issuance of the 1974 regulation?

Answer. The FDA, in June 1974, inaugurated its State contract enforcement program for the diagnostic x-ray equipment performance standard by awarding contracts to seven State radiation control programs. The prime objective of these contractual agreements was to enhance and strengthen the Agency's field observation and enforcement capabilities. Since that time, this number has increased to twenty-two States (see pp. 3–4 in attached BRH Bulletin).[5] These States perform a multiplicity of survey checks (24 test items) such as beam quality (or half-value layer), collimation, linearity, reproducibility, etc., to ascertain compliance status. As mentioned in the response to question 5, these efforts, although chiefly directed at x-ray units subject to FDA's performance standard, are also applied to "old", non-certified machines. This helps to acquire a perspective on the relative effectiveness of the standard in ensuring adequate equipment performance and minimization of the unproductive component of exposure delivered to patients. FDA has budgeted $350,000 for fiscal year 1978 to continue these contracts.

With respect to the second part of the question, it should be noted that inspectional activities are not limited to merely those States under contract. FDA has specialists in the field of radiological health called Radiation Control Officers (RCO's). These individuals, in addition to coordinating radiation control activities among the States within their regions, have performed nearly 3,000 compliance surveys in the 32 non-contract States. The data provided by these surveys are integrated with the information gathered by the twenty-two contract States to give us a nationwide window on the overall performance of diagnostic x-ray equipment.

Question 9. During the hearing, Mr. Gardner stated that "in the next few months" a committee would be assembled to develop some standards for credentialing technicians. Please elaborate. Has the committee been assembled? When will it issue the proposed standards? How would this endeavor be affected by S. 1695, a bill introduced by Senator Randolph? Does FDA support Senator Randolph's bill? If not, why not?

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[4] HEW Publication (FDA), 77–8034.

[5] BRH Bulletin, vol. XI, No. 18, Sept. 26, 1977.

Answer. In the question above, you have correctly noted our stated intention of establishing a committee for the purpose of advising the FDA on the qualifications and credentialing standards for medical radiation technologists. However, subsequent to our appearance before your Committee in June, we reassessed the need for such an advisory committee in light of the Administration's efforts to curtail the number of such advisory groups. In lieu of this approach, we have decided to utilize an existing and viable mechanism for issuing Federal guidance to the medical community. Such guidance is offered by HEW/FDA in the form of recommendations published in the *Federal Register*. These are derived on the basis of extensive clinical and experimental research, thorough documentation, and consensus among professional and consumer groups, Government agencies, individual practitioners, and ancillary personnel. At the present time, a Notice of Intent is being prepared for publication in the *Federal Register* which will announce the Agency's plans to develop recommendations regarding technologist qualifications and elicit information and comments that are germane to the issue for our consideration and use.

With respect to FDA's position on legislation sponsored by Senator Randolph, we should reiterate our response offered to you in reply to a similar question raised in your May 31, 1977, letter. We replied that, "We cannot endorse the approach toward technologist licensure as embodied in legislation presently before the Congress. We believe that licensing is a legitimate State function; the Federal Government's role should be that of a convenor of State and other interested parties for the purpose of establishing standards, which if universally adopted, will ensure uniformity and effectiveness in safeguarding public health."

Question 10. "Please provide the Committee with the status of FDA's attempts at solving jurisdictional disputes with EPA in the issuance of Federal guidance on the medical uses of radiation. Please provide any copies of memoranda of understanding which have been signed since the hearing."

Answer. In our pre-hearing response concerning the issue above, we informed you of the lengthy series of correspondence between HEW and EPA, as well as personal negotiations between the respective agency officials. These talks culminated in a Memorandum of Understanding (copy attached) which was published in the *Federal Register* on January 27, 1977. This MOU provided a mutually agreed upon process by which medical radiation guidance would be developed and issued to the medical and scientific communities.

Since the June hearing, more negotiations between the FDA Commissioner and the EPA Administrator and their staffs have ensued. The focal point for discussion has been EPA's assertion that the terms of the interagency agreement do not apply to its set of recommendations currently being finalized for transmittal to the President (see attached letter). Recently, Commissioner Kennedy has determined that additional dispute of EPA's intention to publish the recommendations for implementation in Federal facilities is not in the Government's best interest. This concession has been made in recognition of the present quadripartite working arrangement between FDA, EPA, OSRA, and CPSC, and to end the jurisdictional dispute between both agencies.

FDA still believes, however, that the integrity of the Public Health Service as the Nation's leader in establishing health care policy must be maintained. Efforts will continue until satisfactory resolution of current concerns with respect to certain EPA recommendations and their potential impact on HEW are achieved.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., August 1, 1977.

MR. DOUGLAS COSTLE,
Administrator, U.S. Environmental Protection Agency,
Washington, D.C.

DEAR DOUG: As we discussed at our meeting on June 17, 1977, I have coordinated a review within HEW of the proposed EPA Federal guidance Memorandum for the President concerning diagnostic x rays. Enclosed are copies of the comments we received from the National Institute of Health, Health Resources Administration, Health Services Administration, Center for Disease Control, Alcohol, Drug Abuse and Mental Health Administration and Health Care Financing Administration. Although these agencies as well as our Bureau of Radiological Health had several technical comments concerning specific recommendations in the package, it is apparent that the major and pervasive concern is for the precedent-setting nature of this EPA memorandum and the ramifications of health care policy-making responsibility being shared by two agencies.

Our discussions of this and related issues have set into motion programs that will result in more coordinated efforts by our respective agencies. As another step in this process, I'd urge that you not send the recommendations memorandum to the President. Instead I'd recommend for your consideration an action that would accomplish the same health goals, but would not raise the issue of a new agency setting health care policy—a matter that deeply troubles all of our sister agencies in this Department. My proposal is that EPA transmit the package to FDA as suggested solutions to radiation problems in medical care facilities, requesting that FDA make formal recommendations based upon them. We in turn would proceed immediately to comply with the request. Swift FDA action on such recommendations would be given high priority, and EPA would be given full opportunity to participate.

This proposal would provide a short-term solution to the issue confronting us. It would also afford us the time to work out a long range solution concerning our respective responsibilities over all ionizing and non-ionizing radiation problems.

Sincerely yours,

DONALD KENNEDY,
Commissioner of Food and Drugs.

Enclosures.

Question 11. Please clarify your response to the question on proposals to establish monitoring systems of individual exposure to medical radiation. In a previous response, you indicated that such a requirement would affect substantially the performance of x-ray examinations. Mr. Villforth supported the idea of individual record keeping, but indicated dosage measurement was a problem. Please explain.

Answer. In order to obtain exposure (Roentgen) or absorbed dose (rad) data for individual recordkeeping, some type of measurement device would need to be placed in or on each patient or between the patient and the x-ray machine. For exposure records, one requires a device that would monitor ionization in air located between the patient and the x-ray machine. Such a device could obscure parts of the radiograph and therefore render the film unusable for diagnosis. In addition, exposure data by itself is inadequate to determine the impact of medical radiation on an individual patient. Knowledge of the x-ray field size and location on the patient, and additional technical data on the x-ray beam quality would also need to be recorded. From the above data one can estimate the absorbed dose to the important radiosensitive organs of the body for a generalized patient, but not necessarily for the individual, because of the large differences in patient size, shape, and anatomy and large variations in x-ray technique. For accurate absorbed dose records, one requires a device to be placed at a suitable location in or on each patient. Dosimeters can be used for surface sites such as skin or testes, but not for deep organs such as the ovaries or the active bone marrow. Such dosimeters, however, could also obscure portions of the radiograph and in general require significant technical expertise to use properly. At present, dosimeter systems that are available are not practical for routine radiology situations.

Question 12. The efficacy study conducted at the University of Washington appears to have been successful in reducing unnecessary patient exposure to x-rays. At page 62 of the transcript, Mr. Villforth stated, "a continuing difficulty is collecting the requisite data base." He noted that the task is an important one, but "there is not a way of collecting this data." Please elaborate on and clarify this statement.

Answer. It should be understood that our success at the University of Washington in reducing the number of skull x-rays for trauma was made possible by the existence of reliable efficacy data in the literature, i.e., information on when such examinations are efficacious and when they are not. Such data, unfortunately, do not generally exist for other examinations, and designing, implementing, and interpreting the kinds of studies needed to derive this data are both expensive and time consuming. First of all existing hospital records generally do not provide enough reliable information on *why* the x-ray was ordered, how it affected the management of the patient, and the long-term outcome of the case. This in turn will require that such studies be prospective in nature, that the hospitals and clinicians involved be prevailed upon to provide the kind of detailed information needed, and that sufficient follow-up time is allowed in order to determine the patient's ultimate clinical outcome. And, since we are often concerned about the probability of determining relatively rare diseases through x-ray procedures, a large number of patients and their records would have to be involved in such an undertaking.

Question 13. Has the FDA considered the impact that medical malpractice legislation could have on reducing patient exposure to unnecessary medical x-rays? If so, please provide the Committee the agency's opinions.

Answer. The FDA's Bureau of Radiological Health has begun to closely examine the possible effects of medical malpractice on the x-ray ordering practices of health care practitioners. The extent of x-ray examinations prescribed solely for guarding against a litigious public is uncertain at this stage in our investigational efforts. Current literature indicates that excessive use of x-rays for medicolegal purposes may reach 30 percent of the 270 million x-ray procedures performed annually. As we noted in our pre-hearing response concerning this subject ". . . although we believe it is difficult to ascribe the requesting of an x-ray examination to purely defensive motives, we believe that the current malpractice environment does cause a number of unnecessary examinations to be taken. The ordering of unnecessary examinations is the greatest contribution to patient exposure and health care costs."

Although we cannot identify what changes would occur as a result of malpractice legislation it would seem logical to assume that whatever legal protection was afforded to physicians from malpractice claims would reduce the incidence of defensive medical practices. Consequently, one would expect a decrease in the number of defensive x-ray examinations. However, we should underscore our belief that the situation would not be overturned simply by passage of a bill. Changes in present behavioral patterns and educational techniques employed in the area of radiology services must be made to complement such legislation in order to insure an orderly transition to more prudent and sound usage of x-rays.

Senator FORD. Our next witness is Dr. William Rowe, Deputy Assistant Administrator for Radiation Programs, U.S. Environmental Protection Agency.

Would you identify those people with you, sir.

STATEMENT OF DR. WILLIAM D. ROWE, DEPUTY ASSISTANT ADMINISTRATOR FOR RADIATION PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY DR. WILLIAM MILLS; FLOYD GALPIN; DANIEL CAHILL; AND ROBERT AUGUSTINE

Dr. ROWE. I am William Rowe, Deputy Assistant Administrator of the EPA. With me is Dr. William Mills, director of our Criteria Standards Division; Floyd Galpin, the director of our Environmental Assessments Division; Dan Cahill, with the Office of Research and Development, who is responsible for research in nonionizing radiation; and Bob Augustine, my chief of operations.

Mr. Chairman, I have submitted a statement for the record, and I have a shorter statement which I will read because of the time limit.

Senator FORD. You can proceed, and your statement as submitted to the committee earlier will be included in the record. I believe that we will request the same from you as we did the previous witness—we may want to submit additional questions or ask you to return for further questioning.

Dr. ROWE. We will be pleased to cooperate with the committee in any way we can.

When we appeared in front of this committee 4 years ago, it was primarily in the context of your review of activities related to the Radiation Control for Health and Safety Act of 1968, Public Law

90–602. In these present hearings the committee has an expanded purview with oversight responsibilities across the whole field of radiation protection in all its aspects. We would like to speak to you from a similar base and in this respect emphasize our role as the focus of Federal guidance.

As you know, before the creation of EPA there was in existence a Federal Radiation Council. This council was created by Executive order of President Eisenhower and was subsequently given a legislative basis by the Congress' codification of its authority.

Primary among its authorities was that it "shall advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards, and in the establishment and execution of programs of cooperation with States."

This role was created so that there would be a focus in the Federal Government for pulling together a complete picture of the radiation problems and advising the President of actions that should be taken. Because of the many diverse areas that radiation impacts and the many sources from which it emanates with a commensurate proliferation of laws and regulations among the Federal agencies to cope with those problems, we are convinced that if this role did not exist that you would have to create it.

In the President's Reorganization Plan of 1970, this authority of the Federal Radiation Council was transferred to the Administrator of EPA. This has been reflected in subsequent legislative codification as presented in 42 U.S.C. 2021.

Although EPA has numerous other authorities that can be used as tools in controlling radiation exposures, it is from this broad perspective that we evaluate the problems, establish priorities, and then determine which of the authorities can most expeditiously solve the problem.

Let me illustrate some of the results of this effort and the way we have applied our authorities to this broad responsibility.

First, in order to carry out such a broad authority one must maintain a cognizance of the totality of radiation protection activities in the United States, and an understanding of the various sources of radiation and their relative contribution to the public's exposure. We have attempted to do this in two ways. To maintain a broad view of radiation protection activities and to inform the public on them, we pull together on an annual basis a report of radiation protection activities. We have published this report for 2 consecutive years and will soon be publishing the third edition.

Relative to documenting the relative impact of various sources of radiation exposure, we publish an annual report titled the "Radiological Quality of the Environment" which covers all sources of radiation. We published the first edition of this report last year and are about to circulate the second edition draft for interagency review as we did the first.

We would be the first to admit that both of these efforts require a good deal of additional refinement. One of the major points that was identified in our first publication of the "Radiological Quality of the Environment" was the many gaps that exist in terms of documentation of the exposure from various sources of radiation. We plan to direct our efforts in the future toward filling these information gaps and toward evaluating the trends that occur over the years. This is an extensive and difficult task and will require our continuing effort.

A third area in which we feel an obligation to provide a broad perspective is in developing the basis of information on health effects of ionizing radiation, which must serve as a consideration in all radiation control activities. To meet this need, we have continued the efforts of the former Federal Radiation Council in funding the National Academy of Sciences, National Research Council, to review the research in this area and formulate recommendations on the appropriate biological exposure.

This work is carried out by the Council's Advisory Committee on the Biological Effects of Ionizing Radiations. Their 1972 report titled "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation" is strongly relied on in our establishment of radiation protection standards and guides.

We have subsequently had the Council examine the problem of biological effects of inhaled alpha-emitting particles. The results of this effort were issued in their 1976 report titled "Health Effects of Alpha-Emitting Particles in the Respiratory Tract."

More recently we have just completed negotiations with the National Research Council for them to again review the research available in the same broad perspective that they did in their 1972 report.

The important point here is, however, that this way of looking at radiation exposure and the associated activities brought to bear on their mitigation has given us a perspective for setting priorities where we can get the most effect for our money.

Now let us look at how we have applied this perspective to some of the specific problems and issues that we have identified. Early in the history of EPA we identified that one of the greatest potentials for radiation exposure of the public, and certainly one of the greatest public concerns, was the nuclear power industry with all of its associated variety of support facilities.

To most efficiently set standards in this area, we chose to exercise those authorities to set generally applicable environmental standards transferred to us from the Atomic Energy Commission by Reorganization Plan 3.

Our first attempt to exercise this authority was aimed at establishing standards for each of the various types of facilities in the uranium fuel cycle. This was called to task by the then Atomic Energy Commission and it was decided at that time that we had overextended our authority by establishing standards on a facility-type basis.

We have subsequently developed limits for radiation protection of members in the general public and for release of long-lived radionuclides applicable across the uranium fuel cycle, and have promulgated standards as 40 CFR 190, "Environmental radiation protection standards for nuclear power operations."

The inclusion of standards for controlling long-lived nuclides and the development of the environmental collective dose commitment concept is a major new step in radiation protection and is being adopted now on an international basis.

Now let me turn to a more recent effort in a completely different area of radiation exposure, that of medical X-ray. In examining the spectrum of exposures from various radiation sources, it was evident that one of the greatest sources was medical X-ray.

Certainly, one of the strongest authorities to cope with this problem was vested in the Food and Drug Administration of the Department of Health, Education, and Welfare in the form of Public Law 90-602 and its authorities for setting requirements on electronic products generating radiation.

Certainly, we would say that the Bureau of Radiological Health, which administers this authority for FDA, has done a commendable job in carrying out these responsibilities.

At the same time, however, there was very little authority in any realm for influencing the way in which this equipment was used.

Furthermore, we continuously heard from the States that their efforts to influence the use of such radiation generating equipment was made more difficult by the fact that those facilities in the Federal Establishment were themselves not all they could be in carrying out good practice.

It appeared to us that the road to improvement could be better paved by establishing guides for Federal facilities under the auspices of our Federal guidance role. All Federal agencies that have such facilities were invited to participate in this effort with us; and all, with the exception of HEW, assigned personnel to serve on task groups to examine the various issues. This included the Army, Navy, and Veterans' Administration. HEW did assign a consultant at the working group level but did not fully participate due to reservations they had about our authority.

Subsequently, we have issued a Federal Register notice of intent to set guides for these Federal facilities. We have also developed an interagency agreement with HEW. However, HEW still questions the authority basis and this basis remains to be resolved.

In any case, we are assured that the guidance, even in its proposed form, will have an influence on practices in Federal facilities and even those in the private sector which will result in reduced exposure without loss of benefit to medical practice. This, we feel, is the true goal of radiation protection.

Now let me cover, in a more summarized manner, some of the other areas where, from our broad perspective, we have moved to reduce radiation exposure.

1. In the early days of the agency we reconfirmed, under our Federal guidance authority, guidance for radiation exposure for uranium miners. These are being implemented by the Bureau of Mines in the Department of the Interior.

2. At the request of the Department of the Interior, we have provided interpretation of Federal guidance applicable to radiation exposures in caves and caverns which exist in our national parks system.

3. In concert with our Federal guidance role and pursuant to an interagency agreement issued in a Federal Register notice of December 24, 1975, titled "Radiological Incident Emergency Response Planning, Fixed Facilities and Transportation," we have issued as agency guidance protective action guides for exposures from accidental release of airborne radioactive materials. These are being slightly revised and will be issued as Federal guidance in the next year.

4. Under the auspicies of the Federal Drinking Water Act, we have issued standards for the content of radionuclides in that media that will limit the public's exposure to 4 millirems per year from manmade radionuclides through that pathway.

Apart from the standards and guides we have set, I must mention another area in which, from our broad perspective, we have greatly reduced the exposure of the public to radiation. This is through our participation in the Agency's exercise of its authorities under the National Environmental Policy Act.

Through our comments on environmental impact statements, we have not only influenced the design and siting of individual facilities but also have influenced major policy decisions at the national level. Although these instances are too numerous to present in detail at this time, they include such matters as the development of the liquid metal fast breeder reactor and the decision of whether to recycle plutonium in the present fuel cycle.

We, of course, also provide overall responsibility for coordination of public health protection in the event of fallout from the testing of nuclear explosives.

Enough about the past; let me briefly summarize some of the issues we see before us and how we are attempting to address these.

1. We are examining the need for establishing Federal guidance in the area of environmental nonionizing radiation. As a part of this effort we are carrying out research on biological effects, and through direct measurements in major metropolitan areas, we are assessing the exposure levels of the population. We have scheduled for ourselves a decision point of March 1978 for the determination of whether such guidance is needed. I will say, however, that the predisposition of my staff is that some type of guidance in this area is required.

2. We are in the final stages of developing Federal guidance for radiation exposures from transuranium radionuclides directly applicable to those areas of this country which have lands contaminated with this material. A draft of this guidance has recently been sent to members of an interagency working group which is assisting us on this matter.

3. We are working with FDA in their development of protective action guides for foods and water contaminated by radioactive materials in the course of a radiation accident or fallout from nuclear weapons testing. We plan to subsequently promulgate these protective action guides through our Federal guidance authority.

4. We are working with an interagency group on the examination of the appropriate standards for occupational radiation exposures. The present limits for occupational exposures in this country were established by the Federal Radiation Council, and we have felt it is time to have these reviewed considering the great deal of additional information that has become available since that time.

5. I would certainly be negligent if I did not mention the effort for which we presently have the greatest commitment of our limited resources. This is the area of criteria and standards for waste disposal, particularly as they relate to the problem of high-level waste resulting from the chemical reprocessing of nuclear fuels. We are working with both ERDA and NRC in this effort of high national

priority. We have attempted to get a maximum public input to this effort and have held two open workshops for this purpose.

6. EPA is also exploring an area of radiation exposure mitigation that has had very little Federal attention up to this time. This is the area of exposure from natural radioactive materials, especially where this exposure has been technologically enhanced by man's activities. Again, from our broad point of view it was evident that the largest source of the exposure to the general population was due to these materials and the cosmic radiations that bombarded the Earth.

Our present efforts in this area have been focused on the phosphate industry and, in connection with our efforts on the uranium fuel cycle, with the uranium milling industry. Further efforts are required in particular related to the matter of radon in the environment in these instances.

However, we have issued interim guidance and plan to soon issue final guidance relative to the pressing issue of reclaimed lands from phosphate mining in the State of Florida.

There are many additional areas we want to examine in the future and for which we feel such examination is a pressing need to resolve vital public issues relative to the public's radiation exposure—such things as low-level radioactive waste and radiations from extra high-voltage lines.

True, we have carried out some field evaluation efforts in these and other areas but we are mostly impressed with how much more needs to be done. Indeed, one of the hardest tasks I have as Deputy Assistant Administrator for Radiation Programs in EPA is focusing our relatively few resources on accomplishing tasks in specific areas when I have in the back of my mind all the areas we are hardly touching.

In closing then, Mr. Chairman and members, I would emphasize that in assuming the responsibilities and authorities of the Federal Radiation Council, we have exercised a broad perspective in the examination of the problems of the public exposure to both ionizing and nonionizing radiations. I offer this committee the utilization of that broad focus as you pursue your new oversight responsibilities. We hope that we can be of assistance to you in bringing to focus the many facets of the issues involved.

Thank you, Mr. Chairman.

Senator FORD. Thank you very much, Doctor, for your more comprehensive statement and your statement here today.

I have a few questions, and I am glad Senator Stevenson is here to assist.

I understand that EPA took nearly 6 years to develop the nuclear fuel cycle standard.

Would you explain why it took 6 years to develop that standard?

Dr. ROWE. Mr. Chairman, when EPA was first formed, it was given certain responsibilities. Those responsibilities were not always recognized by some of the other Federal agencies.

At the same time we had to develop the proper role for EPA, so that we could carry out our responsibilities without duplicating another agency. Finding our way in that area took time. In 1973 we had originally proposed our standards aimed at specific facilities.

At that time a memorandum from the White House suggested that we had gone too far and should not consider each facility, but address the standards across the total fuel cycle. We went back to work and our first question was, could we be effective in setting such a standard?

After some serious examination, not only did we determine it could be effective, but we discovered that the long-lived radionuclides problem was overlooked. Therefore we started again and developed our standard. It took us from 1973 to 1976 to develop that standard, to go through the public hearings that were necessary, and to promulgate the standard.

Indeed, 6 years was a long time. But we needed part of that time to find our way.

Senator FORD. The previous standard was 500. Why was the standard changed to 25? Why was that particular number chosen? What is the nature of EPA's data base and philosophy with this standard?

Dr. ROWE. Well, our base is that we think that any exposure to radiation has some detriment. And that detriment is proportionate to the amount of the dose received.

Therefore, there is no such thing as a safe level. And we have felt, based on this hypothesis, that effort should be made to bring radiation from all sources to a level as low as reasonably achieveable without foregoing the benefit of the activity that must be undertaken.

That is the basic philosophy we used in establishing those levels. We felt that the 25 millirem level was one that could be used throughout the industry, if it was used in good practice, and we felt it was a substantial decrease from the possible exposure level of 500 millirems.

So there was balancing of these two things, and as in any of these matters it represents a value judgment. We have the public input and public hearings to assure that the value judgments we arrived at took into account all sides of the story.

Senator FORD. Doctor, does EPA have a followup strategy to insure that the standard is followed by other Federal agencies and industry?

Dr. ROWE. Yes, we do. The standards that we normally set, such as this one, result in specific regulations developed by other agencies who are responsible for regulation.

The Nuclear Regulatory Commission is responsible for regulation in this area. We are working closely with NRC as it develops regulations to meet our standards, so that when the regulations are promulgated, they will meet our standards, and the practice of the industry as they administer it will also meet these standards.

Now, at the same time we conduct a small level of monitoring either by ourselves or by using information from other people to find out how these programs are doing.

The aim is a general overview. We don't have any extensive monitoring program ourselves to carry this out.

Senator FORD. I refer to a GAO report dated October 26, 1976, concerning an incident at the Peach Bottom Nuclear Plant at Delta, Pa.

It seems there was confusion in determining radiation levels, the sources of the radioactivity and disseminating accurate information to the public.

Apparently, the utility detected radiation in excess of NRC's standards, and initially believed the excess in radiation resulted from an accidental release at the plant, and they sent employees home.

Actually, the increased radiation was due to fallout from a Chinese nuclear test.

Subsequently, the utility, the Commonwealth of Pennsylvania, and ERDA, issued press releases which contained different information.

The State warned the people to wash garden vegetables, and that there might be a dangerously high radioactivity level in milk, but ERDA stated that the level did not present any serious risk.

Under the President's Reorganization Act of 1970, EPA is supposed to have overall responsibility for monitoring all radiation-related activities to determine safe levels of public exposure.

The GAO concluded that this confusion was due to the fact that there were no formal procedures for various agencies reporting to EPA. Thus, EPA was unable to carry out its responsibilities.

Has this situation been corrected?

Dr. ROWE. Mr. Chairman, I think it has. As a result of that incident, we ourselves recognized the problems of communication that were involved, and we established a meeting of the agencies involved, and developed a prototype on how we would operate.

I believe there were seven agencies involved. A prototype, in the sense that we had not formalized it.

In October the Chinese conducted another test. And even with the prototype system, we were immediately able to operate. We had clarified the problems, and I think we demonstrated in response to the second test, even though there was no rainout, that we had a coordinated situation, everybody was on board, and that the public was continuously informed of any problems or potential problems, should they occur.

We now are finalizing this interagency agreement, and we expect it to be completed very shortly. But as far as we are concerned now, it is a matter of formalization.

The steps have already been implemented, and the agencies are working together and have so demonstrated.

Senator FORD. Well, when will these agreements be signed? What is the deadline?

Mr. GALPIN. Mr. Chairman, all of the details have been worked out for the ground level operations relative to that agreement. The only thing that remains to be worked out is interactions with the FAA and ERDA, relative to operations of civil aircraft.

We have been assured by FAA that they have taken this under consideration in a very active manner.

I hope that within the next 2 months we would have such an agreement formalized.

Senator FORD. The reorganization plan of 1970 gave EPA the overall responsibility to coordinate these reporting procedures. This is June of 1977. You have not reached an agreement yet. Is there any reason for taking 7 years to develop an agreement?

Mr. GALPIN. We did not have——

Dr. ROWE. I think—I was going to point out that we have not had many tests in the atmosphere to exercise the system since 1970. It was only when the Chinese test occurred, where there was a rainout, that we discovered that a breakdown in communications existed.

We were perhaps complacent that things were working out all right throughout this period. But this instance pointed out that there was a real problem, and I think we acted as rapidly as we could to correct it.

So I don't think it was a delay in trying to solve the problem. It was a delay in recognition of the problem.

Senator FORD. Has FAA been dragging its feet?

Mr. GALPIN. The difficulty there is determining exactly what information they feel they need at the time an incident such as this would occur, and which is the best source to get that information from.

This has been a difficult situation, both technically, as well as finding the resources within the Federal Establishment to meet those needs.

I would mention that one of the reasons for this is that we have a situation existing now that did not exist in past times of testing, and that is that our aircraft in this day and age fly higher than they used to.

So we have upon us a new technological situation that requires resolution that did not exist before.

Senator FORD. Let's take the Peach Bottom incident again. It was finally determined that there was no accidental release.

But what if the Peach Bottom powerplant had an accidental release. In October 1976, when GAO made its report, how would you have coordinated monitoring and reporting then? Would you have had the same problem?

Mr. GALPIN. No. That would have been a different situation under those conditions.

If they had an accidental release, they would be in a mode of responding and working with local officials as to how to respond to that release under some pretty well-prescribed guidelines that have been determined by a community of Federal agencies which was referred to in setting up the action guides and in guidance that has been submitted to the States, relative to actions that they can take to mitigate those exposures.

So there was on the books, relative to an accidental release, a very well-described set of guidelines for those situations.

Senator FORD. The committee is aware that there are problems in jurisdictional overlap among agencies. What are the problems that you have encountered in that regard? For example, some people cite NRC's emission standards for nuclear powerplants as contrasted with EPA attempts to set environmental exposure standards. What agencies monitor the level of radioactive effluents in and around nuclear plants? Where does NRC's jurisdiction stop and EPA's begin?

Dr. ROWE. NRC is the regulator in this case.

We have set the broad environmental standards.

Now, the NRC is involved in developing their regulations and will set limits for operation which will meet our standards. They have established monitoring systems operated by either the utilities themselves or through the States to monitor each plant's output.

Working with NRC and other agencies over the past years, we at EPA have gone out to various nuclear powerplants and facilities, and gone through extensive studies of how these contaminants, when released from the plant, have pathways to the environment. Based upon these studies, we have been able to develop some very good ways to predict when a certain nuclide is released from the plant and how it will react in the environment.

Our correlations are very, very high. So, we take the data which is supplied from the NRC, and we use these in our model to get an estimate of what the environmental impact is.

Our concern, of course, is that exposure which is outside the fence line, whereas the NRC is concerned primarily with that exposure inside the fence line.

But both of us have concerns that reach across these lines in the sense that I am certain the NRC is concerned about environmental releases, and we are certainly concerned about what the effluent releases are within the plant.

Senator Ford. Doctor, describe in further detail EPA's network of monitoring stations. Are you convinced that the network is capable of detecting localized so-called hot spots and avoiding confusion that was associated with Peach Bottom? Who operates the stations and where are they? What the percentage of the Nation is covered by the system?

Dr. Rowe. Let me turn this subject over to Mr. Galpin.

Mr. Galpin. Relative to the first part of your question as to whether they could determine a localized situation such as Peach Bottom, no. We could not. As it exists today, our monitoring network was not designed to do so. It is designed to look at the ambient environment of what man is exposed to and to look at the trends that occur in that ambient environment and the cumulative and additive releases from all of the sources of ionizing radioactive material.

We are within the purview of the programs of States to be able to first identify localized situations such as Peach Bottom.

We have submitted for the record a description of our monitoring program which provides the number and locations of those stations.

I would mention that the stations are operated primarily by State and local people in an agreement with us, whereby they furnish field measurements and samples, and then submit the samples to our Montgomery, Ala., laboratory for a detailed analysis.

I think you can see that just from this matter of the transportation of the samples of the media to our laboratory for analysis, there is a natural timelag such that one would not be able to get an immediate response or an assessment just from those samples alone.

In this respect, we are very much dependent upon monitoring programs that are operated by the 50 States.

Senator Ford. Who are the individuals that operate the State and local stations?

Mr. Galpin. Oftentimes they are State employees of the responsible agency, or they may be county or local employees.

Senator Ford. Do you ever get volunteers?

Mr. Galpin. On occasion, yes.

Senator Ford. What qualifications does a volunteer have to have?

Mr. Galpin. I don't know that we have set out criteria.

Certainly, under the direction of our Montgomery laboratory, when a station is evaluated, there are sets of instructions as to how to take care of samples, how to install filters, how to take them off, and how to make a field measurement with a detector to give a rough estimate of what those measurements are.

Senator FORD. We are back in the same position as with the X-ray technicians, that they just walk in off the street, the doctor says, "Here is the man. Start the X-rays."

Mr. GALPIN. In terms of a certification program, there is no such program.

On the other hand, I would say that, by far and away, something like 99 percent of these stations are operated by State people with some training by the States in this area.

Senator FORD. You have no criteria for the States that they must follow as it relates to those who operate the stations?

Mr. GALPIN. Not directly relative to operation of the stations. With our Office of Research and Development, we do have a quality assurance program whereby States conducting radio-chemical analysis to determine the radioactivity in various media participate. They make measurements on samples that are of known activity and interchange samples, so that we have a feel for the level of quality of measurements among those making environmental measurements of this type.

Senator FORD. What percentage of the Nation is covered by those systems, those stations?

Mr. GALPIN. Well, we have stations in every State. This is much less than we used to have. We used to have more than one station per State.

Senator FORD. What caused the reduction?

Dr. ROWE. A reduction of resources.

Senator FORD. In dollars?

Dr. ROWE. Yes, sir.

Senator FORD. How much do you pay the States, do you advance money to the States?

Mr. GALPIN. No. We don't pay the States in this respect. It costs us to perform the analysis once they get to our laboratory.

Dr. ROWE. Senator, we do provide the information directly back to the State.

Senator FORD. The equipment is yours and that is your expense?

Dr. ROWE. We supply the equipment. And the State will then make the measurements and take the samples. They send them to us. We make the analysis. And then we return the data to the States so they have it for their use, as well as for ours. So, it is a cooperative program, each of us shares some part of it.

I should also mention that, unlike X-ray technicians, if somebody takes an erroneous measurement, followup to see what caused the erroneous measurement takes place. But such a lapse would not necessarily expose people to unnecessary radiation.

Senator FORD. It is the reverse of that, isn't it? Instead of an untrained individual exposing the population, there is the danger of some exposure that is not adequately monitored and reported?

Dr. ROWE. Well, I think it would be of a different nature here. I think with reasonable traning, most people can do it.

Senator FORD. You stated that an interagency approach is being directed to the problem of management of radioactive waste. Is it true that ERDA is funding a $2 million criteria document for waste disposal which is due in June of next year?

Dr. ROWE. Yes; in December 1976, we were told by the executive branch, namely, the President, that we should set standards for waste management.

And in order to do this, we had to develop a large program for which we had no funds. We undertook to enlarge our staff and began to address the problem immediately. To get the funds for this, we had to go somewhere. It was suggested that ERDA had money for this funding in this area, and, that maybe they could take some of this money and turn it over to us. So this was a transfer of funds whereby we were able to undertake that activity. In no way are the results being implemented for ERDA. They are being implemented independently.

Senator FORD. A low level nuclear waste facility is located in Maxie Flats, Ky. The State officials have called for Federal help with the care of the site. How does EPA interact with State agencies to monitor low-level sites at present and what are your plans for future monitoring?

Dr. ROWE. We have worked very closely with the public health officials in the State of Kentucky. We have initially funded several of the studies that were undertaken to determine the scope of the problem.

And in the State of Kentucky, the people involved have done a very commendable job in carrying out the contracts involved. We have discovered that there are some long-term problems in the way that waste is disposed of. We are continuing to try to look at low-level waste sites and we are going to continue to fund States to help us look at these sites, resources being available.

But the main responsibility for regulation of these sites lies with the NRC. I think they are now actively looking at all of the six commercial sites to see what steps could be taken to address the problem.

Senator FORD. Is there any money available to rework sites?

Dr. ROWE. This is what the NRC is looking at. They are certainly considering the whole gambit of options from doing nothing to completely digging out the sites and replacing them. So, they are making a study of the whole spectrum of possibilities of what might have to be done.

Senator FORD. When will these decisions be made?

Dr. ROWE. I would say the decisions are probably 1½ to 2 years off. But NRC will have to speak for themselves on this. I can't give you the final estimate.

We are working with them to develop those alternatives, because we will have to set standards for low-level waste sites in about the same time frame.

Senator FORD. The committee is aware of the problems that EPA has in coordinating its efforts with other Federal agencies. Some have alleged that EPA proceeds without consulting them, that they get information about EPA's intentions when they read notices in the Federal Register.

The committee has seen documents which indicate that EPA and FDA had serious misunderstandings with respect to determining Federal guidance on radiation protection in the healing arts. Apparently, same scenario is now being played out in your attempt to set up a task force on occupational exposure standards.

How are you trying to avoid these jurisdictional disputes and more effectively coordinate Federal efforts?

Dr. Rowe. Well, the Federal Radiation Council was set up so that the heads of the agencies, all of the Federal agencies involved, were members. When it was transferred to EPA we felt that it was necessary to try to continue the idea of interagency coordination. Therefore, for each area that we have undertaken to address, we have tried to set up an interagency committee to assure that we have coordination and have all of the inputs of participating agencies.

We have done this on medical radiation, on occupational radiation, on the plutonium cleanup standards, among others.

Now, after having invited the people to participate, several agencies have said they would not participate with us, and I don't know what we can do to force them to participate. It is certainly voluntary. It does not commit them to do anything, but to sit down with us as early as possible and work with us.

Senator Ford. Do you need a tough referee?

Dr. Rowe. I think we have got one.

Medical X-rays, for example, since all of our Federal guidance efforts eventually go to the President for promulgation——

Senator Ford. Do we need another act of Congress?

Dr. Rowe. No. I don't think so. I think the President will referee this.

Senator Ford. This one may not be there after 8 years. What do we do after that?

Dr. Rowe. I hope that this is not the case; it will be settled in the next few months.

Senator Ford. The committee has noted reports of the studies on ambient levels of radiation in the environment. They indicate that some areas, such as the Sears Tower in Chicago, have experienced readings of levels in excess of those directed to the U.S. Embassy in Moscow.

What is the Agency doing in assessing the need for a general population exposure standard?

Dr. Rowe. We have a two-pronged effort underway.

Dr. Cahill's effort is aimed at determining what the effects are that occur at levels well below the thermal levels. He will address this if you want him to.

He is looking at some of the experiments that have been carried out by other nations and is trying to reproduce those.

In other words, we are trying to determine what the health effects are.

At the same time we have developed very sensitive monitoring devices in a mobile laboratory. We have been going through the country, city by city, measuring what the ambient environment is. We have covered over 50 percent of the Nation already, and we are continuing this effort.

Sometime next year, hopefully by March of 1978, we expect to have a fix on what the health effects are and a fix on what the levels of the environment are. Based upon this assessment of the scope of the problem, and then using our Federal guidance authority, we hope to promulgate guidance in the area for a general population standard and perhaps even to go into other areas.

Senator Ford. I guess you are spending some $830,000 on a study conducted at Research Triangle Park on exposure from FM radio, UHF, TV, radar, microwave ovens, and so forth. How will this study affect EPA's determination of the need for a general population exposure standard?

Dr. Rowe. That study is one of the two prongs of our effort. Namely, to determine what the effects are. At the same time we are trying to determine the exposure levels. By knowing what the effects and the exposures are, we then can take action to see at what levels we must promulgate to protect the public.

Senator Ford. Is this study enough?

Mr. Cahill. Well, it is not a single study. That is the money and man years allocated to the whole research program. And that $830,000 constitutes the whole program in the EPA investigating the health effects of nonionizing radiation. What we have concentrated on are frequencies which are of environmental importance, the television frequencies, FM radios, and these kinds of things.

And our studies have taken the turn toward replication of Soviet-style experiments. That is, continuous low-power density exposures. We do have a number of results that are confirmatory of Soviet studies. The problem that Dr. Rowe has when he tries to draw a standard and any conclusions from it is that all of these studies have been on animals.

There are extrapolation problems from animal data to humans in all fields of scientific research, but it is particularly bothersome in the field of microwave radiation.

Senator Ford. Other witnesses say much more research is necessary before setting this standard, the exposure standard. Would you agree with that?

Mr. Cahill. Yes, sir, I certainly would.

Senator Ford. How much more?

Mr. Cahill. I honestly don't know the answer to that. It would take a number of years.

Senator Ford. You say a number of years?

Mr. Cahill. Well, all right. To give you an example, in this particular area, microwave or nonionizing radiation health effects, we have excellent coordination throughout the Federal Government by virtue of the coordination provided by the White House's Office of Telecommunications Policy. In 1971 they set up a program that they thought might develop the necessary information within a 5-year time period given a certain number of dollars and man years. The 5 years have come and gone, and essentially we have not solved the problem simply because we need money and the man years that were recommended by the OTP; they were never delivered by the participating agencies.

Senator Ford. Will you get something like that in 1978, do you think?

Mr. Cahill. Not from EPA, no. I don't think so.

Senator Ford. And OTP has done nothing in 5 years?

Mr. Cahill. No. I think they have done the best they can. But they have to come with hat in hand to the agencies and ask for support for these programs. The participating agencies have their own problems and priorities, and this radiation item has not been one of the higher priorities.

Dr. Rowe. I think what Dr. Cahill has said about the priority of nonionizing radiation is a true characterization of the situation. But there is information being promulgated and there is information on the level to which people are exposed. Depending upon the scope of the effects, and exposures, we can determine, we hope, within the next year or so, the scope of the problem. Is it a major problem? Is it a minor problem? Is it somewhere in the middle? Then we can get a better fix on what has to be done. If it is a minor problem, we can probably set an exposure level and get on with other things. If it is a major problem, at least we will have enough information to begin to focus the resources on it and persuade people that these resources have to be focused on the problem.

So we are still, in a sense, in a condition of identification of the scope of the problem. Certainly any research in the area that we undertake will add to our confidence in results. But our first effort is to get an idea of the size of the situation.

Senator Ford. What could speed up the time period in which you are able to make a determination?

Dr. Rowe. Well, the problem is that these experiments take time. We have initiated new experiments. Dr. Cahill can speak about them more thoroughly than I can. But it takes time to set them up and follow them through. So even if a lot of new money were put into this situation, it would still take 2 to 3 years before much of this research could be completed.

We do think the amount that we have going on now, which is certainly not sufficient to do the whole job, will give us a lot of information toward making the first assessment in March 1978.

Senator Ford. You made a very strange statement, that what you need is not additional money, but time. Usually we hear that more money is needed.

Senator Stevenson, do you have some questions?

Senator Stevenson. Yes. I had some questions on this subject, Mr. Chairman. Thank you.

I am concerned about the time taken to make your policy decisions, particularly with respect to energy policies. You say that the "predisposition of my staff" is to some type of guidance in this area, could you be more precise about the predisposition of the staff position? What are your tentative conclusions about the effects of low-level radiation from such sources as microwaves and high voltage lines?

Dr. Rowe. I think the first speaker touched on it to some extent, Senator. The present standard at 10 milliwatts per square centimeter may not be protective of people in so-called hot spots, and there is no time limitation. Thus we feel that there are shortcomings in the existing standard. Whether the addition of a time limit to the existing standard or whether the number should be reduced is something we are not completely sure of yet. But we do feel there is some potential for change. As we have some idea of what the ambient is, we will be able to zero in much more quickly.

Senator Stevenson. Maybe Dr. Cahill would like to respond to some of these questions too. What are people exposed to, what can you tell us now on the basis of your monitoring?

Mr. Galpin. We have pulled together the information from four of the major metropolitan areas that we have surveyed which indicates that there is a mean exposure somewhere around 0.01 to 0.02 microwatts per square centimeter. That is the mean of population exposure. We are estimating with that data something like 1 to 2 percent are exposed at levels above 1 microwatt per square centimeter.

Dr. Rowe. We should mention that the present standard is 10 milliwatts/cm^2, the measurements that we are talking about, are in microwatts/cm^2. So there is a factor of 1,000 between a microwatt and a milliwatt, the microwatt being 1,000 times smaller.

Senator Stevenson. The present standards might not be acceptable though. What would be acceptable?

Dr. Rowe. We don't know yet. That is the problem that we are trying to address.

Senator Stevenson. Can you guess?

Dr. Rowe. No. I have no idea.

Senator Stevenson. Well, what are the effects of low-level radiation from high voltage lines? For example, are you moving toward a national grid that is going to transmit energy to the power stations, power by nuclear energy?

Dr. Rowe. Well, I would say that the effects that we do measure are very much more subtle than those we find from the high levels of microwave radiation or from ionizing radiation. Essentially they are not somatic effects that cause concern, and they do not appear to be genetic effects. The effects seem to be reversible changes in the blood level or other parameters. And I think Dr. Cahill can——

Senator Stevenson. I don't want to ask you to repeat something you said when I was not here. If this is new, let's get it on the record.

Dr. Rowe. That is OK.

Mr. Cahill. Essentially the situation is that the effects of low-level exposure to nonionizing radiation are very poorly known. The effects of low-level electric fields are known even less.

Senator Stevenson. And the studies of other countries tell us nothing?

Mr. Cahill. Well, the studies in the Soviet Union and the East European countries, there have been hundreds of thousands of publications from those areas and up until the past 5 years they have been generally discounted in this country simply because our basic premise was that the only effects from microwave exposure were those attributable to heating. The Soviets proposed that there was more than one mechanism operating, a heating mechanism and some other unknown mechanism. We were just not buying that.

But in the past 5 years in the United States, we in our laboratory and in the other laboratories, have conducted our research as the Soviets had proposed, that is, by prolonged exposure to low power densities, and in fact we are corroborating some of their observations. So I believe at this time we are going to have to lend more credence to the literature that has been developed in these countries. That may give us a fair basis for establishing our own standards.

Senator Stevenson. You mentioned other laboratories. Who else is studying this problem, and what conclusions, if any, have they reached?

Mr. CAHILL. The three major participants in the Federal Government are EPA, HEW, and DOD.

Senator STEVENSON. Have they come to any conclusions?

Mr. CAHILL. No. As I said, it is only in the past couple of years that we in general have decided that we had better take a serious look at the Soviet's way of conducting research.

Senator STEVENSON. And "we" referred to all of the agencies?

Mr. CAHILL. Yes.

Senator STEVENSON. Does NRC devote itself to this area of research, are they concerned about the radiation from the voltage lines?

Mr. CAHILL. Yes, sir. I know that is within their realm of responsibility, but I don't know the status of that. The bulk of the Federal expenditures for health effects research in these areas is carried by EPA, HEW, and DOD.

Senator STEVENSON. ERDA?

Mr. CAHILL. No; they are not active in the nonionizing radiation field. They may have a little bit in the high voltage transmission lines though.

Senator STEVENSON Doesn't the combustion of coal produce radioactivity?

Mr. CAHILL. Yes, sir. It does.

Senator STEVENSON. And the electricity that is transmitted is a result of the generation of electricity from the burning of the coal, and ERDA does not concern itself with either of those sources of radiation?

Mr. CAHILL. I don't think I am qualified to answer that question.

Mr. ROWE. Senator, for radiation present in coal, which is ionizing radiation, we have presently underway at EPA studies to determine the extent of that radiation; to get some idea of the scope of the problem, and what can be done about it. We have found, for example, that precipitators when they precipitate out fly ash, remove a lot of the radioactivity. In fact, we have seen proposals to mine fly ash for uranium, so most of it does not get out into the atmosphere, at least from the uranimum point of view.

However, when we look at the electricity produced and transmitted, which is nonionizing radiation, the evidence is that at relatively low voltage levels such as those on the conventional powerlines, the effects are apparently not very great. We don't know this for sure. But our concern is that many new lines are being designed at much higher voltages, say, 1 million volts. While none of these are active yet, there are plans for installing them. This is why we consider that 60 cycle fields are a very important thing to investigate. We are going to look at these areas in the future.

We have made some initial studies of the field measurements and developed models to predict field strength stat effects are not only health effects but involve environmental effects. People getting shocks, and things like that.

Senator STEVENSON. You said the precipitators have removed a lot of radioactive waste. If there is a disposal of that waste now in large quantities, is it controlled for radioactivity purposes?

Dr. ROWE. At the present time they have not been because it is only in certain areas that this problem occurs. We have been studying which coal veins have high radioactivity, and are tracing what is happening to these materials. It turns out that the radioactivity is found primarily in western coal and very little has been mined so far.

Senator STEVENSON. Most of it is from the western coal?

Dr. ROWE. Yes; and little has been mined.

Senator STEVENSON. The more I hear about coal, and my State has a lot of it, the less enthusiastic I get about it. I don't want to digress, but one of the reasons I say that is because the discharges of CO_2 in the atmosphere has become quite a problem. We are currently considering an energy program which proposes a massive conversion to coal rather than oil and gas for the generation of electricity. Apparently we have no appreciation of the consequences of such a program for the health of the people.

I gather from what you say there are some small fragmented efforts outside your agency on this subject. Do you think there are some institutional changes needed to coordinate and pull together these pieces in order to manage an effective, fast program to give us better information about the dangers from radiation? And I say that not only out of the concern for the health of the people now, but because we need the information in connection with some major policy decisions that are being made.

Dr. ROWE. I assume you are talking about nonionizing radiation.

Senator STEVENSON. I am talking about both.

Dr. ROWE. Let me be as frank with you as I can. I think the outcome of what will be needed for regulation for nonionizing radiation in terms of organization will be totally dependent upon the decisions that we are going to approach in about 1 year. When we have some idea of what the health effects are, and some idea of what the ambient levels are, we can approach the problem. For example, if the health effects are such that the ambient levels are well above the health effect levels then we would indeed need some new institutional change to control this radiation.

If, on the other hand, the ambient levels are well below the levels where we find health effects, what we have going on now is probably suitable. So we have to bring two things together, the health effect levels and the ambient levels together to get an idea of the scope of the problem.

Senator STEVENSON. If I could interrupt right there. You are going to have to do more than that. You are going to have to project what the levels are going to be as a result of the decisions that are being made. It is not present levels I am concerned about as much as it is future levels.

Dr. ROWE. I think you are right, sir. And that is part of our effort. I think we have a good fix on how to do this and so we are really in the area of scoping the problem. If the problem is very large, there will be new requirements for institutional arrangements. If the problem is not too large then perhaps what we have now will be satisfactory with only minor changes. But I think it is incumbent upon us to determine the scope of the problem before we suggest what should be done.

Senator STEVENSON. And you say you will have the problem sized up by March?

Dr. ROWE. That is our goal, sir, to have the problem sized up by that point.

Senator STEVENSON. Without conclusions about it?

Dr. ROWE. No, sir. As we pointed out, the research involved will take considerably more time than that.

Senator STEVENSON. Are you moving as rapidly as is possible or are you restrained by insufficient research?

Dr. ROWE. In terms of monitoring the ambient environment I think we have an adequate base and are moving as rapidly as possible. We couldn't go any faster even if we had more funds; it would take us too long to duplicate the equipment. So we are moving as fast as we can.

In terms of the health effects, certainly increased funding in this area would give us more opportunities to widen the spectrum of experiments, and if they were started early enough the outcome would be in time to affect our decisions.

Senator STEVENSON. It seems to me as if a small increase in expenditures could either end up saving the country $1 billion or the lives of many people, such an increase would be worthwhile. You said your monitoring is quite adequate. Did I understand you earlier to say that you are monitoring the low radiation levels in four metropolitan areas, is that the extent of it?

Mr. GALPIN. Our report was just a summary of four. We have completed seven cities and are right now conducting monitoring on the west coast. We did the east coast and some of the Midwest first. Now we have moved to the west coast. They have some peculiar situations on the west coast that are not prominent in terms of the way the antennas are arranged in their communities.

Senator STEVENSON. Have you monitored Chicago?

Mr. GALPIN. Yes; we have.

Senator STEVENSON. What about rural areas, did you monitor in the vicinity of high voltage lines?

Mr. GALPIN. I would indicate that these surveys we are doing are in the microwave, radio frequency range. We have not been in these metropolitan surveys looking at the high voltage lines, which is of course much, much lower.

Senator STEVENSON. Shouldn't you be monitoring not just the mean levels in large metropolitan areas but also monitoring the exposure of people who live in the vicinity of high voltage lines or microwave transmission stations?

Dr. ROWE. In addition to the mobile monitoring programs you are talking about, we have actually gone out and put monitors around very high sources of microwave radiation and have looked at these throughout the country on the basis of looking at where the high sources are. That work has been pretty well completed and reported upon.

In terms of 60-cycle radiation, we have gone out and made measurements under different types of transmission lines. We have actually developed models to predict what will happen. We have been able to confirm that these models are very good. These measure what people are exposed to but do not tell us what happens because of that exposure.

Senator STEVENSON. What are they exposed to?

Mr. GALPIN. For the microwave type of radiation, as I mentioned, the mean exposure is somewhere in the area of 0.01 to 0.02 microwatts per square centimeter. Some individual exposures are much higher than this. Some building measurements were mentioned before. Where we have found high buildings which are located next to an antenna in another high building, exposures occur that are greater than those for the general population. Certainly in our focus in looking at what might go into standards, this type of exposure would have to receive some special consideration.

Dr. ROWE. I think it is fair to summarize that our initial indications seem to be that there is no major problems at the ambient average exposure at people. But there are many places where people are exposed at higher levels and is where most of our concern will be aimed in terms of the exposure to microwaves.

Senator STEVENSON. And those levels will be much higher in the future if certain decisions are made and even without those decisions, as a matter of fact, with the present technology.

Dr. ROWE. That would certainly seem to be the case, sir.

Senator STEVENSON. Well, this is—I think we have run out of time now—but it is a subject that this committee is going to continue to follow, and especially the Subcommittee on Science, Technology and Space which I chair. As a matter of fact, we hope to continue these hearings next fall. So we will be following your progress closely and with interest.

I hope if there are thoughts as to how we can be of assistance with respect to funding levels, that you won't hesitate to volunteer them.

Thank you, gentlemen. We will be following up with supplementary questions later. Thank you very much.

[The statement follows:]

STATEMENT OF DR. WILLIAM D. ROWE, DEPUTY ASSISTANT ADMINISTRATOR FOR RADIATION PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY

Mr. Chairman and members of the committee, I am Dr. William D. Rowe, Deputy Assistant Administrator for Radiation Programs, U.S. Environmental Protection Agency. I would like to thank the committee for the opportunity to testify before them on the adequacy of current research and regulatory efforts in the area of radiation health and safety.

First, I will summarize the Agency's role in radition protection. EPA's primary radiation protection responsibilities are vested in the authorites transferred to the Agency by Reorganzation Plan No. 3 of 1970. This Plan created EPA. The major functions transferred at that time were to:

Establish generally applicable environmental standards for the protection of the general environment from radioactive material.

Advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. This authority had been previously vested in the President's Radiation Council.

Collect and provide information to the public on environmental levels of radiation.

Provide States assistance.

In additional to the Reorganization Plan, the Agency is authorized by the National Environmental Policy Act to review the environmental impact statements of major Federal actions significantly affecting the quality of the human environment.

Subsequently EPA was authorized to issue permits for dumping radioactive materials into ocean waters and propose and promulgate primary and secondary drinking water regulations.

The Agency has the responsibility to protect the health and welfare of man and the environment from adverse effects due to radiation exposure. This responsibility established EPA in a role to provide continuing Federal overview of radiation protection philosophies, policies and controls. This mandate is achieved by developing policies and controls based on the soundest available scientific and technical information, that satisfy the requirement and intent of the law, that are legally enforceable, and that reflect responsible public policy.

The overall goal of the Environmental Protection Agency implemented through the Office of Radiation Programs is to assure that no avoidable risks occur to individuals, and the population at large, or the environment due to radiation exposure without the existence of offsetting benefits; and within this framework, to minimize risk in a cost-effective manner. To accomplish this goal EPA attempts to be fully responsive to current problems, within the limit of resources available, and to cooperate with other Federal agencies, the States, the public and industry.

Our efforts are directed to specific source-related objectives. These objectives are to minimize radiation exposures to that necessary from: (1) healing arts; (2) industrial applications; (3) nonionizing radiation; (4) natural radioactivity; and (5) nuclear energy applications.

To achieve these objectives in a timely manner, EPA pursues the following general program strategy;

Identify potential radiation problems by assessing their impact on public health and the environment, and determine the trends resulting from radiation source development and use.

Assess the status of current radiation controls, and identify sources and uses with inadequate controls.

Focus on problems based upon their criticality, potential for adverse health and environmental effects, costs, and ability to be reasonably controlled.

Determine the importance of the radiation problem area in addressing national priorities.

Establish radiation standards, guides, and criteria with implementation through other Federal agencies, EPA Reigonal Offices and cooperation with State and local agencies.

Influence radiation policies of other agencies and promote responsible industrial development through this process and use environmental radiation assessment activities to augment guides and standards.

Assess public and private compliance with Agency radiation standards, guides, criteria, and other actions.

In implementing this strategy we are guided by three principles:

Without specific evidence to the contrary, a linear nonthreshold assumption relating radiation exposure to the potential impact on human health is used as a prudent assumption for estimating health risks from exposure to ionizing radiation. Inherent in this assumption is the suggestion that all levels of radiation exposure involve some potential risks to health.

All unnecessary sources of radiation exposure should be avoided; the benefits from exposures must be justified in terms of benefits that would not otherwise be received from the activity causing the exposures; and all doses and exposures should be maintained as low as reasonably achieveable, economic and social considerations being taken into account. These imply a risk-benefit assessment of radiation sources and a cost-benefit assessment of measures which are directed at further reduction in exposures.

Although exposure to radiation from different sources may be associated with the same general effects on health, e.g., cancer induction, the variety of objectives different groups have in establishing radiation protection standards requires a single Federal agency, EPA, to provide national uniformity in radiation control measures from a public health protection perspective.

EPA is emphasizing the Federal radiation protection overview role provided by the authorities of the former Federal Radiation Council. This role has been carried out in a coordinated manner by formation of a number of interagency committees to address specific problems that are of mutual concern to the involved agencies. This approach is being pursued in the areas of medical X-rays, occupational exposures, plutonium cleanup and restoration, management of radioactive wastes, and publication of the Annual Report on Radiation Protection Activities. The exercise of EPA authority to set generally applicable radiation protection standards requires other Federal agencies to implement or enforce EPA's standards and guides under other authorities. EPA is responsible for enforcing standards such as those set forth under the Federal Water Pollution Control (FWPCA), Clean Air Act, and Ocean Dumping Act. In the case of Federal Guidance recommended by the Administrator of EPA for approval by the President, it is up to the Federal agencies to adopt the guidance and to establish enforcement procedures. We believe this approach to standards and guides can minimize Federal duplication and maximize the effectiveness of all Federal radiation control programs.

Radiation research requirements fall into two categories: basic research programs and operation programs. The more basic research programs fall under EPA's Office of Research and Development, and operational programs are conducted under the direction of the Office of Radiation Programs. This split in responsibilities is not only true for radiation activities but also other EPA programs as well. It is similar to the research programs undertaken by the Energy Research and Development Administration (ERDA) and confirmatory research undertaken by the Nuclear Regulatory Commission (NRC). The EPA research and operational needs are developed by means of a matrix analysis which identifies radionuclides of public health concern and sources of environmental radiation in relation to specific research laboratory efforts, and field studies. Such a technique not only identifies the specific research and operational needs, but also provides a means to take into account radiation research efforts by other Federal agencies. This coordination eliminates duplication of efforts and identifies complementary research needs. In this manner, not only does the EPA Office of Research and Development provide response to identified research needs, but also to ERDA and NRC research programs. An operating, working relation with ERDA and NRC has been established to implement coordinated research undertakings.

Nonionizing radiation research is carried out primarily by the Bureau of Radiological Health (BRH) of the Food and Drug Administration (FDA), DOD and EPA. The BRH efforts are directed toward research needed to set equipment performance standards. EPA's efforts are oriented toward ambient and environmental and health effects, and DOD's efforts are directed toward research on bioeffects of particular interest to that department.

In attaining coordination of activities, each Federal agency must retain its legislative mandates, independence of action, and own points of view. Nevertheless, mutual understanding of commonalities and differences in all areas and interchange on technical levels should not in any way compromise the respective roles of the involved agencies.

The Agency's contact with State groups in the radiation protection field are achieved through various means. First the 10 Regional Offices maintain direct contact with the States in their locality, and each Region has a staff member designated for radiation protection activities.

A second means is the Conference of Radiation Control Program Directors, Inc. (CRCPD). This organization is sponsored by EPA, NRC and the FDA of DHEW. The membership of the Conference consists of State and local radiological control program directors. The objectives of the CRCPD are to:

(*a*) Promote radiological health in all aspects and phases.

(*b*) Coordinate radiological health activities of governmental agencies.

(*c*) Encourage the interchange of experience among radiation control program directors.

(*d*) Collect and make accessible to all radiation control program directors in official administrative position such information and data as might be of assistance to them in the proper fulfillment of their duties.

The Federal agencies work closely with the Conference throughout the year to accomplish these objectives. The Agency has found the Conference to be an effective body for assuring coordination between Federal and State radiation control programs.

On several occasions EPA has been requested by a State to assist them in completing a project or performing a study. In these situations EPA coordinates its findings, plans and recommendations with the State authorities.

The Safe Drinking Water Act, which includes control of radioactivity, allows States to accept responsibility for enforcement upon approval by EPA of the State's plan. EPA is required to assist the States to develop their capability to assume this responsibility. If a State cannot or does not accept this responsibility, then EPA is required to implement the Safe Drinking Water Act within that State.

The Office of Radiation Programs (ORP) of EPA operates a nationwide Environmental Radiation Ambient Monitoring System (ERAMS) to provide for the continuing surveillance of radioactive levels throughout the United States and its territories. Through this system, over 7,000 individual analyses are performed annually on samples of air, airborne particulates, deposition, surface and drinking water, milk and human bones. These samples are collected by the State and local health agencies. ORP expands its ERAMS operation through the States after nuclear weapons atmospheric tests are conducted.

In another interagency program with the Federal Preparedness Agency, the Bureau of Radiological Health (BRH) of Food and Drug Administration, Energy Research and Development Administration, Department of Transportation, Defense Civil Preparedness Agency, Federal Disaster Assistance Administration and Nuclear Regulatory Commission, EPA advises and assists the States to develop emergency response plans for radiation incidents involving fixed nuclear facilities and transportation.

EPA has promulgated 40 C.F.R. 190, "Environmental Radiation Protection Standards for Nuclear Power Operations" and 40 C.F.R. 141, "Interim Primary Drinking Water Regulations." The Agency has also reconfirmed guidance for miners in underground mining of uranium ore and provided Interim Recommendations for Radiation Levels on phosphate reclaimed land to the State of Florida.

The agency is currently developing guides:

To control the ambient levels for plutonium in the environment.

For the States, to develop their emergency response plans for transportation incidents and for incidents at fixed nuclear power facilities.

For Federal health care facilities to use for patient exposures from the utilization of diagnostic X-rays in the healing arts.

To control exposure of radiation workers.

To determine the basis for judging as low as reasonably achievable.

Our present standards program includes:

Amending the uranium fuel cycle standard to include the long-lived radionuclide, C–14, tritium, and radon and its daughters.

Developing environmental standards for the disposal of high-level and transuranic radioactive wastes.

Developing standards for other forms of radioactive wastes.

Developing drinking water limits for radon and uranium.

In the field of nonionizing radiation EPA is examining the need to issue guidance. The Agency is primarily looking at those radiations that are typified as microwave or radiofrequency. This effort is divided between the Office of Radiation Programs and the Office of Research and Development (ORD). ORD efforts are directed at evaluating the biological effects of low levels of nonionizing radiations. The ORP effort is related to assessing the current environmental exposures, the potential control methodology, and an evaluation of the impact that the setting of guidance might have. The evaluation of present environmental exposures is being conducted by performing surveys of major metropolitan areas in the United States. The urban areas in which ambient environmental measurements have already been made include Boston, Miami, Philadelphia, New York, Chicago, Washington, D.C., and San Diego. The measurements are made in the frequency bands which had earlier been determined to be those principally responsible for urban area environmental nonionizing radiation levels, i.e., the broadcast radiation frequency bands. Measurements have been made at a total of about 240 locations for all of the cities included in the study to date.

EPA scientists have preliminary findings on health effects in three areas when irradiated laboratory animals are compared to nonirradiated control groups at realtive low-levels of microwave exposure. These are: teratological effects, that is, effects to the fetus of exposed mothers; immunological effects, in that the nitrogen-stimulated lymphocyte response of the animals was changed; and changes in the calcium binding to the surface of the brain tissue were observed on test animals during exposure. As some of these reported changes appear to be reversible and the animals show recoverability after exposure, a major issue that may face us is when can an effect be deemed deleterious.

The nonionizing research of radiation health effects represents the primary radiation bioeffects efforts by the Agency. In fiscal year 1976 OMB decided that EPA would depend on other agencies with larger operating budgets for satisfying its ionizing research needs. The Office of Radiation Programs, therefore, established the means for an effective conveyance of its research and operational requirements to ERDA and NRC. EPA identified four major functional areas, namely: (1) Health Effects, (2) Ecological Processes, (3) Measurement Techniques and Development, and (4) Operational Study Needs. Five problem areas concerned with nuclear energy production were also identified. These were: (1)

Fuel Cycle Operations, (2) Advanced Energy, (3) Waste Management, (4) Transportation, and (5) Accidents. Both functional and problem areas were subclassified. By cross-matching functional and problem areas, EPA diagramatically produced a document specifically designed to express our priority research and operational needs.

In order to establish a programmatic basis of understanding between EPA and ERDA or NRC, several members of the EPA staff, now identified as ORP's "Research Committee," met with ERDA and NRC and were able to identify working groups in NRC and project managers and ERDA concerned with our specific requirements. The two agencies accepted a programmatic overview of our efforts and needs and pledged cooperation.

A part of the OMB decision on research was the provision that a one-year trial period would be used to determine if funding ERDA for ionizing radiation research would provide EPA with needed programmatic data. The question of whether this interagency scheme is paying off via producing satisfactory answers to some of EPA's radiation research and operational needs is now under study. Our effort to convey our programmatic needs to ERDA and NRC appears to be on schedule.

If EPA is going to have a viable means of meeting its radiation research needs through ERDA and their operational needs through NRC, among others, it is imperative that interagency cooperation be improved in the following manner:

Greater commitment to understanding and appreciating our mutual needs.

Assurance by ERDA, NRC, and EPA technical personnel that their administrators support their interagency communication.

More joint projects and contracts.

Greater cross-participation on agency planning and work groups concerned with agency needs.

Assurance by all agencies to make pertinent data and information accessible.

In turn, ORP will have to be able to make its long-term biological effects needs known to ERDA and other agencies so that they will be able to include these projects into their budget cycle.

The Agency's reliance on ERDA for radiation health and safety research is an acceptable means of gathering the necessary information to establish its standards. ERDA, by far, has the largest resources for conducting research into the biological effects of ionizing radiation and the development and institution of radiation measurements. FDA activities are primarily oriented to biological effects and instrumentation associated with the nonionizing radiation area. They do, however, provide some vital information on ionizing radiation effects through their large animal study at Colorado State University and their epidemiological studies. NIEHS has only a minimal effort in radiation research. Neither FDA nor NIEHS can provide a research base as large as that supplied by ERDA.

I would like now to discuss some gaps in radiation health and safety regulatory programs.

Until 1945, the environmental levels of nonionzing radiation were not considered significant. Since then, the electronics, navigation, and communications industries have flourished. There are thousands of sources currently operating and the number of radiofrequency and microwave sources alone is estimated to increase 15 percent annually. While the rate of increase in commercial broadcast stations is declining, the power of some radio and television stations is being increased in order to reach larger audiences. Thus, there are increases in ambient levels of nonionizing radiation at these frequencies.

Certain aspects of nonionizing radiation sources are currently subject to regulation by Federal agencies. The Bureau of Radiological Health of the Food and Drug Administration has authority to establish radiation emission performance standards for electronic products pursuant to P.L. 90–602, but has no authority to regulate the use of such sources. The Federal Communications Commission regulates civilian radiofrequency and microwave sources used in communications and the Office of Telecommunications Policy regulates Government sources, both primarily on considerations of interference and siting. The Federal Power Commission has limited regulatory authority over high voltage transmission lines and the Nuclear Regulatory Commission must consider the environmental impact of high voltage transmission lines originating at nuclear generating plants.

With respect to environmental effects, however, there is yet no control of the ambient level of nonionizing radiation resulting from either point sources or the combination of low levels from multiple sources. The EPA radiation program is providing information on the scope of any environmental problem and, along with other Federal agencies, attempting to assess the magnitude of the potential biological effects on populations. EPA's program also includes development of technical reports and studies of field conditions needed to scope and prepare radiation protection guidance recommendations to Federal agencies for controlling environmental levels of nonionizing radiation.

A possible approach to this problem is for ORP to continue its efforts toward development of nonionizing radiation protection guidance recommendations for Federal agencies and to have the FCC and the OTP utilize such guidance in their regulatory program. With regard to control of environmental hazards from high voltage transmission lines, the same procedure could be used, although the regulatory authorities of other Federal agencies appear quite limited in this regard. Perhaps just the "stature" of Federal radiation protection guidance would have sufficient influence on State regulatory agencies to promote adequate siting requirements or other protective measures.

Another gap in our exposure control concerns naturally-occurring radioactive materials. These materials are ubiquitous in many raw materials and after processing may appear as contaminants in the final product, in by-products, or in solid, liquid, or airborne wastes. Examples of naturally-occurring radioactive materials are uranium and its daughter products including radium, thorium and its daughter products, potassium–40, and naturally-produced carbon–14 and tritium. While in their natural state, these materials generally do not present an environmental hazard or potential exposure to man. However, when removed from the natural state and subjected to some form of processing, these materials can result in an occupational radiation exposure situation, or exposure of the general public through the presence of this radioactivity in construction materials, fertilizers, soil conditioners, and other products, or as air, water, and land pollutants.

A preliminary analysis has been conducted of potential naturally-occurring radioactivity problem areas. A total of 24 production, processing, and manufacturing activities were identified as possibly contributing to radiation exposure of people. In addition, 28 products or classes of products were identified as potentially containing naturally-occurring radioactivity. Possible exposure routes were considered and for each route an estimate was made of the radiation exposure level and the exposed population size to arrive at an index of the potential radiation problem. Federal and State radiation control authorities were also briefly reviewed to determine possible applicability to each problem.

The result of this preliminary analysis indicates that generally there is not sufficient information available to be able to determine the scope or magnitude of each of the potential problem areas. Estimates of the exposure levels and size of the exposed population were really "guesstimates." From these "guesstimates," however, the highest indexes of potential radiation problem are for the utilization of coal as a fuel, coal gasification, uranium mining and milling, production and use of radium sources and devices, direct exposure to building materials, contamination of food by radioactivity in fertilizers, drinking water, radon in structures due to emanation from the water, and direct exposure from contaminated land.

The majority of these potential exposure situations are subject to control under existing authorities. For example, exposure of uranium miners is regulated by the Department of the Interior pursuant to the Federal Metal and Non-Metallic Mine Safety Act. The Department of Labor regulates other occupational radiation exposures under the Occupational Safety and Health Act. Discharges of radioactivity in water or air effluents are regulated under the Federal Water Pollution Control Act and the Clean Air Act. Naturally-occurring radioactivity in drinking water is subject to control under the Safe Drinking Water Act. Radioactivity in food, drugs, and medical devices can be controlled by the FDA. It appears that the Consmer Product Safety Commission could regulate radioactivity in products sold or distributed to or used by consumers. The Department of Housing and Urban Development perhaps can control radioactivity in building materials through its program of specifying minimum Federal standards, and the General Services Administration can set standards for Government purchases and use.

In addition, most States have authority to control exposures to people from naturally-occurring radioactivity, and most States do conduct radiation control programs aimed at radium and other materials. In particular situations, States can prohibit the use of certain materials containing radioactivity, as Colorado has done in regard to the use of uranium mill tailings for construction purposes, and States can regulate the use of land contaminated with radioactivity.

Thus, the problem of naturally-occurring radioactive materials is one of the first determining the scope of specific radiation exposure situations, and then developing guidance that can either be implemented by the appropriate Federal agency or adopted by States in a regulatory radiation control program. Federal guidance is essential to stimulate Federal agency action in implementing their authorities, to assure consistency and compatibility among Federal regulations, and to encourage compatibility among State regulatory programs.

The function "to advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States" was assigned to the Administration of EPA. Pursuant to this authority, EPA would make recommendations to the President and, if approved by the President, these recommendations would be published as guidance to Federal agencies in carrying out their radiation control programs. The Federal agencies would be expected to follow and implement this guidance through their regulatory programs. As part of this authority, EPA also performs a technical overseer role, monitoring those Federal agencies which have a radiation control function to determine if the EPA Federal guidance is being implemented and if indeed the Federal establishment is adequately performing its duties.

When EPA was formed two of the essential elements of establishing Federal guides were underway. The first was a reassessment of all the potential radiation exposures, natural and manmade, to be anticipated. Any recommendation for Federal guidance must be based on such analyses and continually complemented by field monitoring and data from the appropriate Federal and State agencies. This is continuing and is reflected in our Radiology Quality of the Environment Report dated May 1976. This report will be updated annually. The second major effort was to assure that the latest information on the biological effects of radiation are collected, analyzed and distributed for use by those responsible for assessing the impacts of proposed activities. This led to the 1972 BEIR reports of the National Academy of Sciences. Subsequently, we asked the Academy to address the so-called "hot particle" issue and they provided a report on this question in October 1972. EPA is continuing to seek the advice of the National Academy of Sciences and has asked for an update to the 1972 BEIR report. As a result of these efforts, we have developed programs to address those areas where we feel new guidance or interpretation of past guidance is needed.

In closing then, Mr. Chairman and Members, I would emphasize that in assuming the responsibilities and authorities of the Federal Radiation Council we have exercised a broad perspective in the examination of the problems of the public's exposure to both ionizing and nonionizing radiations. I offer this Committee the utilization of that broad focus as you pursue your new oversight responsibilities. We hope that we can be of assistance to you in bringing to focus the many facets of the issues involved.

RESPONSE TO QUESTIONS FROM THE SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION, JUNE 13, 1977

The Committee would appreciate receiving your views on the following items. You may deviate from the format set out below; it is intended to suggest the type of information the Committee wishes to include in the hearing record.

Question 1. Status of efforts to set Federal individual and population exposure standards. This may include a discussion of the standards for both ionizing and nonionizing radiation, including the basis for these standards.

Answer 1. Under the Federal guidance authority, EPA is currently developing guides for radiation protection in several areas. These include control of ambient levels of plutonium in the environment, protective action guides for radiological emergency planning, guides related to patient exposure from the utilization of diagnostic x-rays in the healing arts, guides for the control of radiation exposures to workers, and criteria for radioactive waste management. It is expected that the recommendations for plutonium and diagnostic x-rays will be completed in the current fiscal year. It is anticipated that recommendations for occupational exposures and protective action guides for gaseous radioactivity releases will be completed in FY 1978.

With respect to generally applicable environmental standards, amendments to EPA's uranium fuel cycle standards are being developed to cover long-lived radionuclides, such as carbon-14, tritium, and radon and its daughters. It is expected that the carbon-14 amendment will be completed in FY 1979, with the others to follow if necessary. Efforts have been accelerated to develop environmental standards applicable to the disposal of high-level radioactive wastes, with promulgation expected in 1978. Other forms of radioactive wastes will be the subject of future standards. Also under consideration for FY 1979 are additions to the safe drinking water regulations to provide for control of radon and uranium.

In establishing our standards and guides, EPA relies heavily upon health risk estimates contained in the 1972 National Academy of Sciences' BEIR Report. In instances where there is newer information pertaining to health effects, this information is also factored into our estimates of the health impact. As a prudent measure, perhaps overly biased toward added public health protection some would say, the Agency has assumed a linear, non-threshold relationship between the amount of radiation dose received and the induction of a biological effect in using such health impact estimates. It should be mentioned here that we have contracted again with the Academy to update the 1972 report and we expect a new report from the Academy by the end of 1978. Having performed the risk estimates, we also examine the technology available to control exposures and the cost-effectiveness in risk reduction. Underlying our whole philosophy of protection is a value judgment that the activity producing the radiation exposure will have some benefit and that we expect radiation exposures to be kept as low as reasonably achievable. Both of these concepts are in concert with the admonitions of the former Federal Radiation Council and expert bodies such as NSRP and ICRP.

EPA is also examining the need for issuing Federal guidance in the area of environmental nonionizing radiation. The current effort is primarily related to microwave and radio-frequency radiation. Within EPA this effort is shared between the Office of Radiation Programs (ORP), and the Office of Research and Development (ORD). ORD efforts are directed at evaluating the biological effects of low levels of these radiations. The ORP effort is related to assessing the current environmental exposures and the potential control methodology, and evaluating the impact of Federal guidance. The assessment of environmental exposures is being conducted by performing field studies of major metropolitan areas in the U.S. and is about 50 percent completed. Efforts on control methodologies and the impact of potential guidance or standards are just beginning.

A decision will be made in March 1978 as to the need for Federal guidance for environmental exposure to nonionizing radiation. If needed, such guidance would be developed in FY 1979. The only U.S. standards in this area at the present time are based on recommendations of the Aemrican National Standards Institute (ANSI) and have been adopted by OSHA for controlling occupational exposure.

EPA's standards are not based upon industry recommendations but are based on independent evaluations performed by EPA. However, in developing these standards EPA does seek. through public comment and hearings, the opinion of industry, members of the academic community, other Federal agencies, environmental organizations, scientific and technical organizations, and the public at large. Through such a procedure, EPA maintains its independence but is able to consider and reflect the views of various interested parties.

Regulations or Federal guidance promulgated by EPA which include radiation protection are the following: (1) 40 CFR 190, "Environmental Radiation Protection Standards for Nuclear Power Operations"; (2) 40 CFR 141, "Interim Primary Drinking Water Regulations"; (3) 40 CFR 220–229, "Ocean Dumping"; (4) 40 CFR 125, "National Pollution Discharge Eliminaton System"; and, (5) 36 FR 9480, "Underground Mining of Uranium Ore—Radiation Protection Guidance for Federal Agencies." In addition to these, radiation protection guidance has ben provided to the National Park Service ("Interim Recommendations on Exposure Limits—Carlsbad Caverns," 41 FR 2409), and to the State of Florida ("Interim Recommendations for Radiation Levels—Florida Phosphate Lands," 41 FR 26066). Copies of these are attached.

Question 2. The extent and nature of monitoring, surveillance, inspection, or other regulatory efforts in the area of ionizing and nonionizing radiation. A description of the data collection and/or analysis systems associated with these activities. A description of procedures followed when events occur which require notifying the public of potential hazards: for example, occurrence of a radiation accident from a nuclear power plant.

Answer 2. EPA has "regulatory" responsibility in only three areas related to radiation exposure. These are (1) ocean dumping, (2) drinking water, and (3) discharge permits for radioactive materials not included under the Atomic Energy Act. In the area of ocean dumping, the Agency is preparing criteria to serve as a basis for the potential issuance of permits. As a part of this effort, we have conducted surveys at past dump sites to ascertain condition of materials previously disposed of in this manner. In the drinking water regulations, it is expected that most of the responsibility will be assumed by States who accept primacy under the provisions of the Act. However, there will be some States which will not accept primacy, and in these EPA must assume the regulatory responsibility directly. This will include carrying out monitoring of drinking water supplies in conformance with the requirements of the safe drinking water regulations.

Under the discharge permit authorities, the discharger is primarily held responsible for measuring his discharges to assure that they are in conformance with the limits of the issued permit. However, there are some compliance checks made on a routine basis.

Apart from these "regulatory" efforts EPA conducts extensive monitoring and surveillance activities for ionizing radiation. Since its existence, and by its predecessor organization in DHEW, EPA has operated an environmental radiation monitoring system, which is now primarily oriented to ascertaining the ambient levels of radiation in the environment. More detailed discussions of this system are presented on pages 36–40 and 203–247 of the *Radiological Quality of the Environment Report* and page 102 of the *Radiation Protection Activities Report—1975*, both of whish are atached. The Agency also conducts surveillance at specific types of nuclear facilities and facilities which generate effluents containing natural radionuclides in order to assess these problems and determine the need for and level of appropriate standards and guidance. A list of representative studies is attached.

In the nonionizing area, as was mentioned under Answer #1, the Agency has performed a number of surveys of metropolitan areas to ascertain the levels of nonionizing radiation to which the general public is exposed. We have also conducted a number of more source-related studies, examining the potential of hazards from specific sources. A list of these studies is also attached.

Relative to the procedures to be followed in the event that public notification is required, most of these actions are a firstline responsibility of other agencies or their licensees. For instance, in the case of an accident at a nuclear power plant, it is the responsibility of the power plant operator (an NRC licensee) to notify Federal, State, and local public officials, and it is in the purview of the State public officials to notify the public as to what action, if any, they should take. As a secondary role, NRC or ERDA will notify EPA so that we will be cognizant of the situation and be able to answer public or press inquiries from our perspective. Relevant to all accidental radioactivity releases, EPA has the role of providing guidance to the States as to actions that can be taken to mitigate the exposures in these incidents and the levels of potential exposure at which these actions should be considered (Protective Action Guides).

Question 3. Discussion of any formal understandings between EPA and other Federal agencies in the area of radiation research, control, monitoring, etc. For example, how are the environmental responsibilities of EPA being coordinated with OSHA, NRC, and FDA? Please provide copies of letters of understanding or agreement. Discussions of any need for legislative changes in order to facilitate coordination.

Answer 3. With respect to EPA's standards and guidance authorities, the Agency has attempted to work closely with other Federal agencies having specific interest in a particular area involving individual or population radiation exposures. To assure consideration of such interests in the development of Federal radiation guides, the Agency has established interagency working groups which serve not only to provide information and advice but in some instances aid in the technical development of the guides themselves. In this context, working groups have been used for developing guides for diagnostic x rays in the healing arts, exposure guides for radiation workers, and the control of plutonium in the ambient environment. Invitations to participate in the interagency working groups are provided from the EPA Administrator to the heads of various agencies. We have had varying degrees of participation by representatives from NRC, ERDA, FDA, DOD, VA, DOS, HUD, and DOL. In the promulgation of radiation protection standards, the established Agency procedures are followed for review and public comment. Copies of Memoranda of Understanding pertaining to our cooperative efforts with DHEW on diagnostic x rays and with NRC pertaining to permit requirements under the FWPCA are attached.

In the area of high-level radioactive waste management, EPA and ERDA are in the final stages of negotiating an interagency agreement pertaining to the development by EPA of a draft generally applicable standard for high-level wastes by December 1977. ERDA has recognized the need for such a standard and has transferred up to $2,000,000 to EPA for funding assistance in this effort. A copy of the EPA–ERDA draft Memorandum of Understanding, proposed interagency, agreement, and related correspondence are attached.

In addition, EPA has contracted with A. D. Little, Inc., to conduct a technical analysis in support of EPA's environmental standards for such waste. EPA obtained a formal understanding with ERDA to permit the contractor to consult with ERDA contractors and technical personnel. This arrangement was established to avoid duplication of effort for technical and scientific control measures. Copies of the pretinent correspondence are attached. A similar effort has been initiated by EPA with NRC (copy of correspondence attached).

With regard to shallow-land burial of low-level radioactive wastes an informal interagency coordination committee, consisting of members from EPA, ERDA, NRC, and USGS, has been formed. The purpose of this committee is to exchange information on the programs and activities of those agencies in the area of land burial of low-level radioactive wastes, with the objective to develop a coordinated national program for the management of low-level radioactive wastes.

An interagency agreement between EPA and NOAA provides for cooperative efforts in a program of ocean disposal site baseline surveys and evaluations, including those for radioactive waste disposal, pursuant to PL 92–532, the Marine Protection, Research and Sanctuaries Act. A copy of this agreement is attached. Other interagency agreements to which EPA is a party include the following, copies of which are attached:

(1) An agreement with NASA provides for EPA to conduct an off-site radiological health and safety program in support of certain space launches which involve radioactive materials.

(2) An agreement under the auspices of GSA relates to Federal agency activities in providing guidance and assistance to States in developing emergency response plans for nuclear facility and transportation accidents.

(3) Another agreement under the auspices of GSA provides for coordination of Federal agency activities in the time of national emergencies, such as war.

(4) An agreement under the leadership of ERDA (Interagency Radiological Assistance Plan) and a separate agreement with U.S. Air Force ("Broken Arrow" incidents) cover the response of EPA radiological assistant teams to various types of nuclear or radiological emergencies.

(5) Under the auspices of the President's Office of Telecommunications Policy, there is an agreement which deals with Federal agency cooperation in evaluating effects of nonionizing radiation.

(6) An agreement with ERDA provides for interagency cooperative efforts in evaluating any potential adverse effects of extra high-voltage electrical transmission lines.

(7) In FY 1977, ERDA through an agreement supported the continuation of EPA research on health effects of krypton-85. This research project would have been terminated along with other EPA research programs in ionizing radiation.

(8) Through an interagency agreement with the USAF Electromagnetic Compatibility Analysis Center, EPA has access to information on the nationwide locations of nonionizing radiation sources and their specifications. Such information is vital to the assessment of population exposures to environmental nonionizing radiation.

EPA is currently arranging a Federal interagency agreement to provide for cooperative efforts in case of fallout from nuclear weapons testing. The arrangements relative to ground operations have been completed and only those related to civil aircraft operations are still under discussion.

With regard to agreements for cooperation in the area of ionizing radiation research, meetings have been held with both ERDA and NRC to discuss the research needs of EPA and to establish working relationships. Copies of correspondence related to these discussions are attached.

At this time there is no need for legislative changes to facilitate Federal agency coordination. The authority of EPA "to advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States" is adequate to assure coordination of radiation protection activities among Federal agencies.

Question 4. Description of administrative arrangements within EPA which have evolved in order to continue the responsibilities of the Federal Radiation Council which were transferred to the EPA.

Answer 4. The responsibilities of the former Federal Radiation Council were assigned to the Administrator of EPA, when the FRC was abolished. Thus, the advisory role to the President, formerly accomplished by the Council, is now solely the responsibility of the Administrator. In practice this means that Federal guides are recommended by the Administrator for approval by the President. The development of such guides is the responsibility of the Division of Criteria and Standards within the Office of Radiation Programs. The Office of Radiation Programs is under the Deputy Assistant Administrator for Radiation Programs and the Assistant Administrator for Air and Waste Management.

The Federal guides are developed in consultation with interagency working groups which are made up of representatives of the various Federal agencies having an interest or expertise in the area concerned. Internally, the development of guidance is assisted by an intra-agency working group and is reviewed by the Agency's Steering Committee. The Steering Committee serves as the principal advisory committee to the Administrator pertaining to the promulgation of Agency recommendations. Subsequent to the Administrator's final decision, formal comments from Federal agencies and other groups may be sought prior to submission of the recommendations to the President for his approval.

Question 5. Comments on decisions to depend on ERDA for radiation health and safety research more heavily than upon FDA or NIEHS or other similar agencies. Comments on reports that there have been disagreements between EPA and OSHA over responsibilities for occupational exposure control, and between EPA and FDA over dosage levels for diagnostic or therapeutic radiation.

Answer 5. Reliance on ERDA for ionizing radiation health and safety research is a means of gathering the necessary information for EPA to establish its standards. ERDA has the largest resources for conducting research into the biological effects of ionizing radiation and the development and institution of radiation measurements. FDA activities are primarily oriented to biological effects and instrumentation associated with the nonionizing radiation area, but do provide some information on ionizing radiation effects through their large study at Colorado State University and their epidemiological studies. NIEHS has only a minimal effort in radiation research. Neither FDA nor NIEHS provides a research base nearly as large as that supplied by ERDA.

The disagreement between EPA and OSHA over responsibilities for occupational radiation exposure levels revolved around EPA's use of its Federal guidance authority and the regulations developed by OSHA. OSHA depends primarily upon criteria documents prepared by NIOSH for promulgating its regulations. However, in writing their regulations on occupational exposure to radiation, they have relied upon the 1960 Federal guides published by the former Federal Radiation Council. EPA currently is in the process of revising these 1960 guides to reflect more recent information, such as in the 1972 BEIR Report on biological effects and changes in radiation worker experience.

The disagreements between EPA and FDA concerning radiation protection in the use of diagnostic x-rays in the healing arts have been over which agency has primary responsibility to provide basic guidance for this source of population exposure. EPA is utilizing its Federal guidance responsibility to develop guides concerning patient protection in those Federal facilities providing direct medical care. FDA argues that the Reorganization Plan No. 3 of 1970 provided DHEW with the full responsibility to make recommendations pertaining to the practice of medicine and dentistry. These issues have been under active discussion between the agencies involved, and we are moving toward a resolution in the near future.

Question 6. Levels of effort employed in evaluating and resolving issues of public interest, such as claims that there are potential health and environmental hazards associated with extremely low-frequency radiation (e.g., the Navy's proposed project Seafarer), from the proliferation of microwave communications devices, from magnetic fields from high-voltage transmission lines, and from future applications of such concepts as space collection and conversion of solar energy and transfer to earth by microwave. Any other comments on current and future concerns.

Answer 6. The levels of effort associated with these nonionizing radiation problems are small in number and have been focused on the matter of assessing the need for an environmental criteria or standard. EPA studies so far indicate that radio-broadcast activities account for more population exposure than the microwave communication devices mentioned in the question. These efforts were previously discussed in the answer to Question No. 1. The annual levels of resources applicable to these areas include $830,000 for biological effects research and $200,000 for environmental assessment. The knowledge gained from this effort, especially on biological effects, will be applicable also to the other areas of nonionizing radiation concern.

The only specific effort that has been directed at the proposed Project Seafarer has been to comment on EIS's and to conduct liaison with other Government agencies that are involved. In the areas of high-voltage transmission lines, the efforts have been only slightly more than cognizance. Some work was done for the Nuclear Regulatory Commission (NRC) in assessing the environmental levels associated with Extra-High-Voltage (EHV) lines and we have prepared a report which shows that one can adequately predict the electric fields associated with high-voltage transmission lines without the necessity for conducting field measurements in every case. In that connection, we believe that these electric fields offer more potential for harm than do the magnetic fields mentioned in this question. EPA issued a *Federal Register* Notice (*FR* 40:53, 12312), dated March 18, 1975, requesting information on fields associated with EHV, to which we received voluminous replies. Our preliminary analysis of this information indicates that there does not appear to be any short-term or acute effects that are evident from such exposures. The Agency is presently negotiating with a contractor who will review and summarize the information received so that it can be issued to the public. There have been no specific efforts directed to such concepts as microwave transmission of energy from satellites or other futuristic applications and concerns. We have interacted with DHEW relative to the matter of the use of lasers in public demonstrations and have agreed with that agency on methods of approach for handling this problem.

Question 7. Where are the EPA laboratories which are conducting radiation research? What expenditures of money and manpower are devoted to such labs? How are their efforts coordinated with those of other agencies? What are EPA plans for eventual expansion or reduction in this area? What decision processes are followed in assigning tasks to NIEHS or ERDA rather than to EPA labs?

Answer 7. The Radiation Health Effects Research Program is located at the Office of Research and Development's Health Effects Research Laboratory in Research Triangle Park, North Carolina. The program deals with nonionizing radiation with emphasis on the development of exposure systems of environmental importance, e.g., FM radio, UHF-TV, radar, and microwave ovens. These systems are used in whole animal and celluar studies. The biological parameters investigated include teratology, immunology, spontaneous and learned behavior, cytogenetics, reproductive genetics, and biochemical and biophysical effects. The studies range from those at the macromolecular level to those using bacterial and human cell lines to those using animal models, i.e., mice, rats, hamsters, dogs, and monkeys.

The Fiscal Year 1977 budget for this program is $830,000 and 30 full-time permanent positions. The Fiscal Year 1978 allocation is projected at the same level. This program constitutes about 15 percent of the Federal effort in nonionizing radiation.

The Radiation Health Effects Research Program is coordinated closely with EPA's Office of Radiation Programs, and in turn with EPA's representative to the Office of Telecommunications Policy which coordinates nonionizing radiation research. Through this mechanism, the plans of the various agencies engaged in nonionizing radiation research, such as EPA, NIEHS, and ERDA, can be interfaced.

Further, the staff of the Health Effects Research program maintains its own formal and informal contacts with other agencies, including FDA's Bureau of Radiological Health, the National Institute of Environmental Health Sciences, and the Energy Research and Development Administration. The staff has, for example, participated on ERDA review teams both at the Battelle Northwest and the Argonne National Laboratories.

While EPA's support of an ionizing program was phased down by the end of Fiscal Year 1976 because of the establishment of ERDA which has a large expertise in ionizing radiation, a cadre of scientists was maintained whose expertise includes a capability for evaluating ionizing radiation health effects data coming from studies in other groups. In addition, the ERDA supports some work on krypton-85 in the Research and Development Laboratory, because of that Laboratory's unique capability and expertise for the projects. It may also be noted that ERDA supports a program at Research and Development's Environmental Monitoring and Support Laboratory in Las Vegas. This program deals with the bioavailability of actinides, primarily plutonium and americium.

Resource considerations will be developed as part of the Agency's Zero Base Budgeting for Fiscal Year 1979.

Question 8. EPA reaction to state radiation control health officers' recommendation that Federal radiation activities be clarified or centralized.

Answer 8. EPA's FRC authority currently has the broad and comprehensive responsibility to serve as a focal point for national radiation protection policies and for developing recommendations for Federal guides. EPA will continue to work with the State radiation control health officers and assist them with the problems they may have with Federal radiation activities.

Question 9. A description of changes in EPA programs which have resulted from reduction or redistribution of funds appropriated for radiation programs. What cuts in reporting, monitoring, and other public protection programs have occurred?

Answer 9. The principal change in EPA programs resulting from reduction in resources has been the necessity to reassign a greater share of resources to the development of standards, primarily at the expense of our direct laboratory operation and State support programs. With respect to the Federal Radiation Council function, now the responsibility of EPA, the nature of the Council was to utilize working groups which had at their command the large resources available to the secretary-level members of the Council; thus, the transfer of four positions from FRC represented only a small fraction of the manpower utilized by the Council. It is this manpower shortage that EPA has had to overcome by the transfer of ORP laboratory positions to standards development. This loss is compounded because we have also lost internally the availability of scientific expertise in radiation protection, because of the necessity by the Agency to use those experts and radiation research positions to address other pollutants.

Some of the more severe impacts due to reduction of funds have been in the areas of monitoring and reporting of information on radioactivity in the environment. For instance, EPA had to execute a reduction in force in December 31, 1974, which resulted in abolishing the Reports Branch of the Field Operations Division. The primary output of that Branch was to produce the monthly publication, *Radiation Data and Reports.* This publication included the radiation data from the EPA Environmental Radiation Ambient Monitoring System as well as environmental radiation data from the States and other Federal agencies.

Reduction in funds and resources have also led to a cutback in EPA's environmental radiation ambient monitoring activities. Several media were dropped entirely. Except for milk, we terminated the sampling of food. The human bone from autopsies and institutional diet sampling were also dropped. Our air monitoring programs were reduced to 19 continuous stations and 48 standby stations from the previous level of 72 continuously operating stations. The sampling of milk was reduced from a weekly frequency to a monthly frequency, and the number of surface water sampling stations were greatly reduced. It should also be mentioned that these budget reductions have resulted in a slow down of the number of directed field studies that the Agency has been able to perform. As mentioned earlier, laboratory support to State radiation control programs has been reduced.

Question 10. Discussion of any problems being encountered by EPA in interagency agreements, resolution of responsibility for broad environmental programs as opposed to more specific programs (e.g., NRC emission standards for power plants vis-a-vis EPA's attempts to set environmental exposure standards). What efforts are devoted to monitoring the soil, air, and water around nuclear power plants to determine actual emissions and possible accumulation in ecosystems? Could or should more be done? If so, how much more, and by whom, and at what level of funding?

Answer 10. With the exception of the disagreements referred to in Question 5, EPA has had major interagency difficulties only with ERDA. These difficulties have arisen primarily over questions of radioactivity in water. As a result of this disagreement, limits for radioactivity in drinking water were delayed for a year and EPA has not proposed water quality criteria under the FWPCA. In lieu of such criteria the Agency is currently relying on the radioactivity limits promulgated pursuant to the Safe Drinking Water Act.

EPA has experienced minor difficulties in its high-level waste program with ERDA and NRC; however, these difficulties appear to be reaching satisfactory resolution. With respect to EPA's uranium fuel cycle standards, there was an earlier disagreement between NRC and EPA regarding the scope of any proposed EPA standards pertaining to the nuclear industry. This question of scope was satisfactorily resolved by the Executive Branch, providing EPA a charter to write standards which apply to the whole uranium fuel cycle, rather than specific types of facilities. NRC is currently developing regulations which will fully implement the EPA standards.

Relative to the efforts that are devoted to monitoring at nuclear power plants, the basic responsibility for the day to day monitoring is assigned to the operator of the facility at the direction of the Nuclear Regulatory Commission (NRC). These programs are usually comprehensive and include sampling of air, water, foodstuffs, and other elements of the food chain. It is estimated that the cost of these efforts are on the order of $70 to $120 thousand per year per facility. As there are 66 facilities in the United States licensed to operate, this represents a full resource commitment of $6 million or more. The EPA has conducted in-depth evaluations of four facilities to determine a generic picture of the environmental consequences of their operations. These studies were funded at about $200K each, for a total effort of $800K. The Agency has also conducted subsequent evaluations at nuclear power plants related to more specific problems such as radioactive iodine contamination of the environment, direct radiation from the facility, and the potential buildup of radionuclides in a confined cooling lake. Evaluations of this type are funded on the order of $100K each. Although the monitoring efforts conducted by the facility operator are, in general, adequate, there are definite improvements that could be made in terms of data analysis and reporting. Also, there is a need for an independent evaluation of facilities which would involve occasional checking of environmental levels to confirm the operator's conclusions. EPA has long felt that this is a responsibility that it should undertake but limited resources have prohibited it from carrying out this activity. It is estimated that such evaluations could be done at the cost of around $50 to $100K and one man-year's effort per facility checked. If EPA were to do 5% of the facilities each year, the cost of such a program would be around $350K with the present number of plants. As the number of facilities increases, more resources would be required.

Question 11. Identification of specific areas of research or regulation or where actions cannot be undertaken until more data are available.

Answer 11. In the consideration of the need for regulatory controls of environmental nonionizing radiation, there are several areas where more information is needed. The first of these, and the most important, is in the area of biological effects. Present standards for nonionizing radiation in this country are primarily based on biological effects associated with the thermal impact of nonionizing radiation. Studies in other countries, primarily Eastern Europe, have indicated more subtle effects and have served as a basis in those countries for standards several orders of magnitude lower than those in the United States. Recent efforts by EPA researchers show indications in animal studies of effects to immunological systems, fetusses born to exposed mothers, and changes in calcium binding to the surface of brain tissue. Because these results occur at exposure levels below those associated with the thermal (body heat) effects previously used as a basis for US standards, there is an urgent need to perform additional research to confirm or discredit these preliminary results. Associated questions relate to the ability to extrapolate from these animal studies to the potential effects on humans and the evaluation of "to what extent one deems deleterious an effect which allows recovery after exposure." Other areas for which additional data are required are the costs of control, including impact on Federal agencies, and an improved delineation of the general population exposure to these radiations.

In the consideration of standards for uranium mill tailings as a part of low-level waste standards and the consideration of the inclusion of radon in EPA's uranium fuel cycle standards, there is a need for more data on control measures and the effects and dosimetry of radon emanations.

The most important research needs of the Office of Radiation Programs are the following:

I. Transuranic Toxicology and Pathway Studies:

Subject large laboratory animals to chronic, low level exposures of alpha and beta emitting transuranic radionuclides via inhalation techniques to determine deposition, organ sensitivity for specific cancers and latency periods.

Determine the mutational rates for the testes and ovaries due to alpha particle irradiation.

Conduct experiments with transuranic elements to identify regions of nonuniform (hot spot) deposition in various organs, particularly the testes and ovaries in relation to age. Radiation dose should also be calculated per unit weight of organ for both large and small male and female laboratory animals.

Determine effects of various chemical forms of Am and Pu, as found in contaminated soil, on uptake by animals.

II. Non ionizing Radiation Toxicology:

Define specific absorption frequencies in simple biological systems by exposing selected polypeptides, bovine serum albumin, and cells to a spectrum of microwave frequencies over a range of 250–8000 MHz.

Conduct animal experiments using chronic exposures at a variety of frequencies including 2450 MHz at power densities ranging downward from 10 $mWcm^2$. Chronic exposure studies need to resolve Russian and European claims and must provide an insight to testicular, genetic, developmental, ocular, growth, endocrine, hematopoietic, immunologic, nervous system and behavioral changes, malignancy and any possible induction of malignancy.

Conduct similar studies following high peak, low average power pulsed, non ionizing radiation exposures.

Conduct animal ecological bioeffect studies to determine the health and environmental effects from extra-high voltage overhead power transmission.

Feasibility studies are needed to find specific biological monitors, such as EEG's and circulating adrenal corticosterone levels, that will be useful in epidemiological studies.

Epidemiological studies are needed and should address behavioral, immuniological and teratological parameters in addition to special biological monitors yet to be determined.

III. Emission, Measurement and Toxicity of Radon and its Daughters:

Develop dose models for estimating population exposure from radon emanating from natural sources, uranium mill tailings piles, potable water, and into structures:

Develop low-cost instrumentation to detect radon levels on the order of 0.01 working levels. Develop methodology for sampling and measuring radon and its daughters in aqueous media such as potable water and geothermal fluids.

Conduct epidemological studies of U.S. uranium miners, U.S. hard rock or metal miners. Studies should note cancer incidence and death rates, histologic diagnosis of cancer, teratogenic bioeffects and chromosomal aberrations in peripheral lymphocytes. Environmental stresses other than ionizing radiation need to be evaluated and factored into the radiation epidemiological analyses.

IV. Age Sensitivity to Ionizing Radiation:

Subject a variety of animals to acute and chronic whole-body exposures (x or γ rays) to determine the dose/effect response during several stages of life, namely: fetal, newborn, immature, mature, old age.

Conduct similar experiments for internally deposited alpha particle emitters by both inhalation and ingestion.

V. Remedial Measures for Uranium Mill Tailings Piles. Determine cost-effective methods to control radiation exposure from active and inactive uranium mill tailings piles. Study should address alternatives to earth cover, control of material and longevity of dikes, and methods appropriate to the ultimate decommissioning of a mill facility.

VI. Radioactive Wastes:

Develop an appropriate environmental pathway-dose calculational model for radioactive materials released from radioactive waste repositories.

Evaluate the radiological impact of a "direct conversion fluid bed fuel fabrication facility."

VII. Uranium:

Develop a data base to evaluate the radiological impact of *in situ* leaching of uranium deposits and heap leaching of uranium ore.

Develop a more efficient quantitative analysis for natural uranium in water.

Question 12. Administrative structure of EPA. How are radiation responsibilities divided, e.g., between regional offices, headquarters, and the laboratories.

Answer 12. The responsibility for radiation programs in EPA is primarily with the Office of Radiation Programs (ORP). Other Agency components with radiation responsibilities include the ten Regional Offices and the Office of Research and Development. The Office of Radiation Programs is headed by the Deputy Assistant Administrator for Radiation Programs, who reports to the Assistant Administrator for Air and Waste Management. The Assistant Administrator reports to the Administrator of EPA.

ORP responsibilities include development of radiation protection criteria, standards, and Federal guidance; technology assessment; and environmental analysis. This includes monitoring, surveillance, field studies, and other activities to meet operational needs. Two ORP field facilities (laboratories) provide technical support to the Program.

Radiation research in EPA, which now is limited primarily to nonionizing radiation only, is conducted by the Office of Research and Development through its laboratories. As noted in Answer #7, the nonionizing research program is coordinated with and in response to the needs of ORP. The Office of Research and Development also provides the Agency's Quality Assurance Services which are available to all laboratories including State and private laboratories, to assist in maintaining accurate radioanalytical measurements.

The Regional Radiation Program staffs, which consist of only one or two professionals in each Region, are the representatives of the Agency for radiation matters within their Regions. They are responsible for the day-to-day interactions with State and local agencies, the public, news media, industry, and others on radiation problems of mutual concern. They serve as the radiation experts within the Regional Offices providing consultation and advice to other components of the Regional Offices, as well as to the States and the public. Technical backup, if needed, is provided to the Regional Programs by ORP Headquarters and Laboratory staffs, but the Regional Radiation Programs are the main point of contact and coordination within the Regions. The Regional Radiation Program staffs report through a chain of command to the Regional Administrators, who report to the Administrator of EPA.

Question 13. Capability of EPA to respond to emergency radiation incidents. Coordination of EPA programs with civil defense programs.

Answer 13. It should first be noted that except for its voluntary participation in the Interagency Radiological Assistance Plan and Air Force Response Plan, previously discussed under Question # 3, EPA has no functional role in actual response to emergency radiation incidents. EPA's role is that of providing guidance to other Federal agencies and to States as to actions that can be taken and the levels of projected exposure (Protective Action Guides) at which action should be considered. EPA would also be expected to provide guidance and direct assistance when called upon at the actual time of an incident. The one exception to this advisory and guidance role is in the case of fallout from nuclear weapons testing at which time EPA has the operational responsibility to carry out monitoring and assessment and to gather data from all Federal agencies and States in performing such assessment. It is the EPA's responsibility under these circumstances to notify the public of the national situation and any general action that it deems is required. The initiation of action on a localized basis is still within the purview of the States. The coordination of EPA programs with Civil Defense programs is carried out through the interagency agreements related to peacetime and wartime radiation incidents that were discussed under Question # 3. Both the Federal Preparedness Agency and the Defense Civil Preparedness Agency are party to these interagency coordination efforts with EPA.

Question 14. Discussion of status of state and EPA responsibilities: are the divisions clear, or are there gaps in jurisdiction?

Answer 14. In addition to Federal radiation control authorities, most of the States possess authority to control certain aspects of radiation. Many of the Federal statutes either mandate that States promulgate and enforce regulations, or permit the Federal authority to be delegated, through agreements, to the States. Where there is no Federal regulatory authority to control certain aspects of radiation, most of the States have enabling statutes and regulatory programs for such control.

Federal statutes that either mandate establishment of State regulatory programs, permit delegation to States, or permit assumption by States, include the following:

Resource Conservation and Recovery Act.
Safe Drinking Water Act.
Occupational Safety and Health Act of 1970.
Federal Water Pollution Control Act, as amended.
Atomic Energy Act of 1954, as amended.
Clean Air Act, as amended.

As of June 30, 1974, a total of 47 States and Puerto Rico have enacted specific laws providing for the regulation of ionizing radiation. In the other States and the District of Columbia, authority for some aspects of radiation protection is assumed under general public health laws. State programs generally encompass regulation of x-ray facilities and use, all radioactive materials not included for control under the Atomic Energy Act and for those States who have agreed to do so, regulation of radioactive materials formerly under the control of the Nuclear Regulatory Commission.

Pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, the Nuclear Regulatory Commission may enter into agreements with States providing for the discontinuance of the regulatory authority of the Commission with respect to one or more of the following materials within the State:

1. Byproduct materials.
2. Source materials.
3. Special nuclear materials in quantities not sufficient to form a critical mass.

During the duration of such agreement, the State has the authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards. As of December 31, 1974, 25 States have entered into such an agreement and now conduct a regulatory radiation control program for these materials.

As of June 30, 1973, 16 States had enacted legislation providing for the regulation of nonionizing radiation and four States have specific legislation for the registration of laser devices. In addition, five States and Puerto Rico have specific laws which establish minimum standards for the education, training, and experience of certain user groups that apply ionizing radiation to human beings for diagnostic or therapeutic purposes.

In an effort to achieve compatibility and some degree of uniformity among State radiation control programs, a document entitled *Suggested State Regulations for Control of Radiation* was published by the Council of State Governments in 1962 with the assistance of the U.S. Atomic Energy Commission and the U.S. Public Health Service, and periodically revised and updated. The Office of the Nuclear Regulatory Commission, the Food and Drug Administration, the Conference of Radiation Control Program Directors, Inc., and the Council of State Governments. Generally, most State radiation control regulations have been developed to be compatible with applicable parts of the Suggested State Regulations, but, of course, vary in comprehensiveness and effectivenes.

Although not necessarily a problem between EPA and the States, there are situations which represent a gap between Federal and State jurdisdiction. An example of one such situation is the responsibility for financing the cleanup of abandoned uranium mill tailings piles in the West. ERDA and EPA, at the request of the Joint Committee on Atomic Energy, were required to analyze the problem and determine a feasible solution. There remains some confusion between the States and the Federal Government over which one will finance the cleanup and restoration of these lands.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND EPAs RESPONSES

Question. The Committee is in possession of the 1975 Annual report on Radiation Protection Activities. If a more recent report has been issued, please provide the Committee a copy. Also, the Committee would appreciate seeing the second edition draft of EPA's report on the Radiological Quality of the Environment. Also, please provide the Committee's EPA's report on measured levels of microwave radiation (East Coast and midwestern cities).

Answer. EPA has recently published its 1976 Annual Report on Radiation Protection Activities. A copy is provided as attachment 1 EPA report number 520/4–77–005. A p reprint copy of the 1977 edition of "Radiological Quality of the Environment" is provided as attachment 2. Available in Committee files. A draft copy of the report "Nonionizing Radiation Levels and Population Exposure in Urban Areas of the Eastern United States" and the report "Nonionizing Radiation Exposure in Urban Areas of the United States" are provided as attachments 3 and 4. Available in Committee files.

Question. Please provide the Committee a detailed legislative history of the authorities of the Federal Radiation Council and the Atomic Energy Commission which EPA inherited, including citations to relevant statutes and executive orders.

Answer. The Federal Radiation Council (FRC) was established by President Eisenhower in 1959 through Executive Order 10831. Congress provided a statutory basis for the FRC by passage of Public Law 86–373, which incorporated the functions laid out by the Executive Order into the Atomic Energy Act. The FRC was disestablished and its functions transfered to the Administrator of the Environmental Protection Agency by Reorganization Plan No. 3 of 1970. This authority is encoded at 42 U.S.C. 2021(h).

Also transferred to EPA from the Atomic Energy Commission by Reorganization Plan No. 3 was the authority ". . . of establishing generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." This authority is contained in the AEA as amended, principally in Section 161(b).

Other legislative authorities which provide EPA with a statutory basis for providing radiation protection are contained in the following Acts:

Safe Drinking Water Act (December 16, 1974)
Clean Air Act Amendments of 1977 (August 7, 1977)
Resource Conservation and Recovery Act of 1976 (Oct. 21, 1976)
Federal Water Pollution Control Act Amendments of 1972 (September 28, 1972)
Toxic Substances Control Act (October 11, 1976)
Marine Protection, Research, and Sanctuaries Act of 1972 (October 23, 1972)

Question. During the hearing, Dr. Rowe mentioned a major new step in radiation protection—"the environmental dose commitment concept." Please explain in further detail.

Answer. The environmental dose commitment concept was developed to assess the impact of a radioactive material present in the environment for an extended period of time, allowing for changes in the population exposed as a function of time. It is the sum of all doses to individuals over the time period that a radioactive material released to the environment is available for interaction with people. Thus it encompasses all of the radiation dose delivered to a population, which can vary over time with changing environmental conditions. It differs from those assesments which focus only on individual dose, or on annual population dose. A publication detailing this concept is provided as attachment 5. (EPA report number EPA 520/4–73–002)

Question. Mr. Galpin admitted that ERAMS was unable to detect localized "hotspots", but that it was not designed to do so. Do you think that it is possible to modify ERAMS to make it responsive to localized danger situations? In your opinion, ought the detection of localized hot spots continue to be a State responsibility?

Answer. EPA's Environmental Radiation Ambient Monitoring System (ERAMS) does not usually detect localized "hotspots" because the fixed sampling stations are very thinly spread geographically. Each State has primarily only one station for air particulates and one for pasteurized milk. Only a few States have two or three such stations. A brochure describing the ERAMS is provided as attachment 6. Available from U.S. Government Printing Office 1974–643–904/ N.P.

The purpose of ERAMS, as its name implies, is to measure general ambient radiation levels with an orientation towards assessment of population exposures and trends in the general environment. The present station locations have been somewhat oriented to assess population exposures near nuclear facilities but the coverage is inadequate to entirely determine the influence of facilities. The surface water sampling network of ERAMS is the most facility oriented part of the system. However, the frequency of sample collection from rivers is inadequate for detecting short-term faciity discharges. Overall, ERAMS is considered as a "bare bones" system with regard to adequacy for evaluation the general ambient radiation environment. It is not designed for obtaining detailed regional information. In addition to the fixed station ERAMS, EPA can acquire regional or facility oriented data by special field studies. Such field study capability could be provided on short notice, if warranted.

EPA is also signatory to the Interagency Radiological Assistance Plan (IRAP) which makes this Agency's resources available when requested by a State. Should a localized emergency occur, such as a nuclear facility accident, two actions could be taken. First of all, samples could be rushed to EPA's Montgomery, Ala., laboratory by the Air Force or commercial aircraft to speed up the process. Or, on a longer term basis the mobile laboratory headquartered at Montgomery, Alabama, could be moved to such an accident location to assist in the radiological assessment. While these actions would not be of assistance in either detection or assessment during the first few hours after such an incident, they could be valuable in the longer term evaluation and cleanup activities.

It is difficult to imagine establishing a centralized Federal program that could be depended upon to detect localized "hot-spots." Relative to nuclear facility related incidents, the Nuclear Regulatory Commission requires monitoring both on-site and off-site, which should be able to give an initial evaluation. Furthermore, States are asked to develop emergency plans to carry out radiological assessments where there are nuclear facilities. Federal agencies, through a formal Interagency Agreement, are actively working to assist States in developing such emergency plans and preparing to implement them. It should be noted that any emergency response authority and responsibility relative to the public lies with the States. Although Federal Guidance has been developed and is continuing to be developed, the responsibility to take action lies with the States. The States then are the place where the most immediate need for radiological assessment exists.

Unfortunately, the ability of all States to perform radiological assessments is not uniform. Some States are capable of complete assessments while others have very limited environmental programs. A few States have to rely entirely on ERAMS for their information. This situation regarding State capability is most troublesome to us and Federal assistance may be needed to provide incentives to States in this area. The data from improved State environmental radiological assessments would also be of great assistance to EPA in preparing its national assessment.

In summary, it is EPA's opinion that the detection of localized hot spots should continue to be a State responsibility, but that most States are inadequately set up to meet this responsibility. At present EPA has no grant programs to provide the assistance to States in this area.

Question. With regard to your local stations: Can you even be reasonably sure of the reliability of field measurements when the station volunteers are not asked to meet any requirements? What does this imply for the effectiveness of your network?

Answer. Although there are no defined requirements for local ERAMS station operators it should be understood that they are not "men off the street" volunteers. A station operator is typically a health professional and is most often a part of a State Radiological Health Program. Furthermore, the methodology for collecting field samples is relatively simple and completely set forth in an instruction manual provided to each operator. It should be noted that all samples, including air filters which are the only samples on which field measurements are made, are sent to the Eastern Environmental Radiation Facility in Montgomery, Alabama, where they undergo thorough analysis in the laboratory.

ERAMS is geared towards broad geographical coverage for situations like widespread fallout from atmospheric nuclear weapons testing. For these situations, radioactivity levels do not suddenly increase at one station. Rather, radiation levels go up slowly over areas covered by several stations. Therefore, a station failure or single operator error is not necessarily crucial to the entire system. In cases where there is wide divergence between field estimates and laboratory results (some difference is expected) there is a followup with the station operator by EPA. In summary, the ability of station operators is not a limitation on the effectiveness of the ERAMS Program.

Question. In your discussion of the Peach Bottom incident, you said that it was not until the test occurred that you were aware of the problem in communication. Are there any evaluative efforts going on now to determine any other potential breakdowns?

Answer. The communication breakdown referred to is that the Nuclear Regulatory Commission had not been officially alerted of the possibility of radioactive fallout from the nuclear detonation by the People's Republic of China on September 26, 1976. Therefore, they had not notified their licensed facilities and the staff of the Peach Bottom reactor initially interpreted their environmental radioactivity measurements as potentially from their facility. The possibility of this situation recurring has been alleviated through agreement on notification procedures among concerned agencies. This agreement is being formalized through an Interagency Memorandum of Understanding (MOU) which will be discussed in more detail later. I will be standard operating procedure to update the communications contacts between agencies every 6 months to assure that future communications breakdowns do not occur. EPA has also devised an internal operating plan that should assure that its role is adequately fulfilled. The two subsequent nuclear tests on November 26, 1976, and September 17, 1977, where both the interagency MOU procedures and the EPA internal operating procedures were followed, have indicated that communications are now satisfactory.

Question. You state that each of EPA's ten regional offices maintain direct contact with States in their locality and each regional office has a staff member designated for radiation protection. How much of that individual's time is spent on radiation protection?

Answer. EPA has a total of 18 radiation protection professionals distributed among the 10 Regional Offices. One of the primary responsibilities of the Regional Radiation Protection Programs is to maintain direct contact with State and local radiation control programs and to provide information and technical assistance to the States. The Regional Offices are the link between the headquarters component of EPA and the State programs. The amount of time the Regional radiation staff devotes to radiation protection varies among the Regions, but it is estimated that overall approximately 75–80 percent of their time is spent on radiation protection.

Question. According to Dr. Ellett from EPA's Office of Radiation Protection, there are 20 active monitoring stations and 54 inactive ones. How much additional money would be required to activate the remaining 54? Would this additional cost be justified? What about the possibility of interacting with ERDA monitoring systems? Would this significantly aid EPA's efforts?

Answer. Currently, there are 22 ERAMS air sampling stations in continuous operation and 45 on standby. An additional $40,000–$50,000 would be needed to operate all 67 stations on a continuous basis (2 samples per week). In view of the fact that these stations would likely be measuring only background levels of radioactivity except in cases of fallout from nuclear testing, continuous operation probably could not be justified. General geographical coverage of the U.S. under normal conditions is currently provided by the 22 continuously operating stations. The additional technical information obtained by operatig all 67 continuously would be of relatively little scientific value, although some benefit might be derived from additional coverage for public assurance. During a fallout alert, such as when a foreign atmospheric nuclear test occurs, all stations are requested to run continuously. In addition, all stations are activated for a period of time each year as a test, regardless of whether any nuclear detonations have occurred.

About 15 ERDA facilities that have environmental monitoring programs do report their data to EPA during fallout alert periods. These data are helpful in supplementing ERAMS data. However, each facility only monitors locally, so their data does not greatly add to completing the national picture. The primary value from ERDA facility data is that each facility can quickly make detailed measurements on samples taken nearby. Therefore, ERDA may be able to relay on to EPA the earliest detailed indications of the presence of radionuclide fallout in a given area. This is particularly important for ERDA's facility in Richland, Washington, where the first arrival of contaminated air masses over the U.S. typically occurs.

Question. Would it be feasible or desirable to add equipment in order to monitor levels of nonionizing radiation at selected ERAMS stations?

Answer. The addition of nonionizing radiation detectors at selected ERAMS stations does not appear to be an effective approach to assessing environmental levels of onionizing radiation. The stations are not well located for this purpose and the station operators are not experienced with this type of measurement which is much more sophisticated. These radiations are more localized to sources, such as radio transmitting towers, and the required equipment is quite elaborate and expensive. It is our opinion that the most cost-effective method for assessing environmental levels of nonionizing radiation is through periodic surveys with an elaborate system such as included in EPA's Mobile Electromagnetic Radiation Analysis Van.

Question. Perhaps the most disturbing aspect of the late Atomic Energy Commission's activities was its radioactive waste legacy. Millions of gallons of wastes are now languishing in tanks all over the U.S., and both NRC and ERDA have been slow to move on this problem. What is EPA's opinion of the possible environmental hazard posed by these wastes? What recommendations does EPA have for dealing with these wastes? What statutory authority, if any, does EPA have in this situation?

Answer. EPA has reviewed the Environmental Impact Statements (EIS) regarding the waste management operations of the Federal Government's facilities near Richland, Washington; Savannah River, South Carolina; and Idaho Falls, Idaho, where more than 99 percent of the defense programs high-level liquid radioactive wastes are currently stored. As a result of these reviews, EPA concluded that these waste storage operations have not caused any significant radiological effect on the general public or to the environment at the present time. However, we are concerned with the potental impacts on the environment and public health over long periods of time. EPA is of the opinion that current large inventories of high-level wastes and their continued production suggests there is a potential for significant impacts which warrant resolution of this problem. The Environmental Protection Agency believes that disposal of radioactive wastes requires satisfactory execution of three important programs: 1) Statement of requirements for protection of the environment and public health; 2) Development of technologies and sites, and the conduct of operations for disposal of radioactive wastes that can satisfy environmental and public health requirements; and 3) Regulation of activities at specific sites to assure overall safety, including environmental and public health protection. The responsibility for the first program lies with EPA; the latter two are the responsibility of the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC), respectively.

The responsibility for setting radiation protection standards for radioactive wastes is vested in two authorities transferred to EPA by Reorganization Plan No. 3 of 1970. The first of these is the broad responsibility to provide Federal radiation guidance for all radiation directly or indirectly affecting health, which was derived from the former Federal Radiation Council. This is the only comprehensive radiation protection authority at the Federal level; most radiation protection authority is vested in regulatory agencies for specific problem areas such as regulation of nuclear power, worker safety, regulation of electric products which emit radiation. etc. The second authority transferred to EPA by the Reorganization Plan specifies setting generally applicable environmental standards outside the boundaries of sites which possess radioactive materials that are subject to regulation under the Atomic Energy Act. This circumstance establishes an interface between EPA and other agencies wherein they implement and enforce standards set by EPA. Likewise, EPA needs to be responsive to the needs of other agencies for standards for problem areas such as radioactive waste. EPA coordinates its standards and guidance activities with other agencies in an attempt to prevent duplication of effort or other jurisdictional problems.

Question. Aside from nuclear wastes, reactors themselves pose a potent radioactive threat. The present jurisdictional alignment prevents EPA from setting standards directly affecting ERDA and NRC; however, the agencies are supposed to meet effluent release guidelines. Does EPA consider the present arrangement satisfactory? How could it be improved?

Answer. It is not necessary that EPA be given the responsibility to directly establish effluent release standards for the emission of radioactivity in order that public health be protected. We believe our present authority makes EPA the lead Agency for making determinations on the degree of radiation protection required for the protection of the public health and the environment. We believe, also, that DOE and NRC respect this leadership. NRC is proceeding to implemnet our standards for nuclear power in a satisfactory manner. Jurisdictional issues no longer appear to be a difficulty. In addition to our authority to set general standards for DOE operations under the Atomic Energy Act, we now also must control air releases under the Clean Air Act, as amended, and promulgate limits applicable to such facilities. We also could establish Federal Guidance for such facilities.

Question. Since there appears to be a gap in control over naturally occurring radioactive materials, which agency would be best suited to exert such control? Which agency has the best statutory claim to this responsibility?

Answer. Although there are some minor gaps in the control of natural radioactivity, these are principally due to the diversity of sources and authorities which exist for controlling such sources, and not to lack of authority. These authorities reside principally in EPA, with some additional responsibilities in various agencies, such as the Department of Health, Education, and Welfare, the Consumer Product Safety Commission, and the Nuclear Regulatory Commission. EPA has a variety of applicable authorities including the Resource Conservation and Recovery Act of 1976, the Clean Air Act, as amended, and the Toxic Substances Control Act of 1976, as well as its overall Federal radiation protection guidance function. Any gap in control that exists is caused by this spread of authorities and the inherent difficulties of assuring consistency of regulation. EPA is continuing to explore the scope of this source of population exposures and will use the most appropriate of our several authorities to achieve control that is warranted. We do not believe that, at present, any new statutory definition of agency responsibilities is required.

Question. In addition to natural radiation, accelerator-produced radioactive materials are supposed to be a potential problem in exposure control. You suggest eight applicable authorities for regulation. You seem to suggest that EPA develop Federal guidance which would stimulate other agency action in implementation. In view of your limited research resources and dependence on ERDA for other research needs, the fact that you only have "guesstimates," and the interagency "turf" problems EPA has had, do you really think such an arrangement would be coherent and efficient?

Answer. We have every reason to be optimistic that we will be able to bring about the radiation protection control required for these sources of radiation. These sources constitute an extremely minor part of the total public radiation hazard. To the extent that these sources do constitute any problem, they are principally an occupational exposure hazard. EPA's Federal guidance authority includes, as a major responsibility, Federal guides for occupational exposure. Development of Federal Radiation Guides is conducted in cooperation with other Federal agencies and EPA intends to use all available sources of information, including that from various research programs. Therefore, the lack of EPA research resources, per se, is not a critical deterrent to this development. Keep in mind that Federal guides, approved by the President, carry a rather strong incentive for conformance and we will followup to the extent of our resources to assure this conformance.

Question. With respect to the January 1977 memorandum of understanding on Federal guidance on diagnostic and clinical x-radiation: Has that memo resolved your jurisdictional problems with FDA-BRH at all? If so, please explain. If not, what further remedies are being explored?

Answer. The Administrator of EPA and the Commissioner of FDA have agreed that this issue will be resolved and that the two agencies will cooperate under the terms of the Memorandum of Understanding. I am optimistic that these guides will be submitted to the President for approval very soon. We are very pleased that this major step will be taken to provide radiation protection for for patients in Federal facilities.

Question. With respect to the radiation emitted from high voltage transmission lines and from coal-fired plants: In each case, which agency will assume regulatory jurisdiction? What criteria will be used to assert jurisdiction?

Answer. With respect to radiation (electric and magnetic fields) emitted from high voltage transmission lines, EPA has not at this time determined that there is a need for Federal regulatory control. Our preliminary evaluation does not indicate any immediate effects are occurring from these radiations. However, our evaluation has been minimal due to the priority of other activities. Should more thorough evaluation at a later time indicate the need for Federal control of these emissions, several options appear possible. The one selected would depend of the degree of the problem and applicability of control option. Initially, EPA could work with the Council of State Governments to prepare draft recommended State legislation and regulations for control. Then, if the problem appears to require it, EPA could request legislation authorizing specific standard setting and regulatory control in this area.

With respect to the emissions of radioactivity from coal-fired plants, this material is natural in origin. We have the authority to establish air emission standards pursuant to the Clean Air Act, run-off to water pathways pursuant to the Federal Water Pollution Control Act, and the disposal of waste materials pursuant to the Resource Conservation and Recovery Act. Although at present, releases from such plants are under study, they may not be a significant source of exposure. However, we will continue to maintain an appropriate degree of awareness of this potential source and take steps to control is as necessary.

Question. With respect to low-level effects of ionizing radiation, is EPA aware of recent studies of Dr. Sternglass relating fallout from the Chinese nuclear tests to higher infant mortality rates in New England? If so, does this indicate a need for change in radiation protection philosophy or in specific exposure or emission standards?

Answer. EPA is aware of Dr. Sternglass' reported association between fallout from Chinese nuclear tests and higher infant mortality rates in New England. Dr. Sternglass presented his controversial findings to the Biological Effects of Ionizing Radiation (BEIR) Committee of the National Research Council/National Academy of Sciences on July 18, 1977. This Committee has been contracted by the Environmental Protection Agency to review the biological effects of ionizing radiation, similar to its 1972 study. Although Dr. Sternglass' report gives no cause for modifying radiation protection philosophy or standards, the BEIR Committee is considering his presentation in their development of their new report. We have tested Dr. Sternglass' hypothesis that there is causal relation between infant mortality and I–131 in milk. Analyses of all the data by Spearman's test for rank correlation and Kendall's test for independence show that there is little chance that infant mortality is correlated with the integrated I-131 consumption following the Chinese nuclear tests. We note further that Dr. Sternglass' data appear to be incomplete in that existing data from States showing an effect opposite to that which he proposes were omitted.

Question. You have stated that interagency cooperation needs to be improved in several respects. Your suggestions indicate apparently serious deficiencies in the present system. Can you document occasions where agencies refused to provide each other access to pertinent data, or where administrators refused to support technical personnel's communication?

Answer. At times in the past there has been a major problem. However, in the last few years since the demise of the Atomic Energy Commission this has become less of a problem. Our relations with NRC are very good and those with DOE rapidly improving. In general EPA has received good cooperation with DOE and NRC with regard to radioactive waste issues. It appears we will also have good cooperation in regulating under the Clean Air Act.

EPA's most serious problems with other agencies lie with the non-proliferation initiative and the program being developed by DOE and Department of State. Recently DOE has cooperated with regard to the nuclear alternatives program (NASAP). However, we are not always kept abreast of the programs of these departments and it has only been through sustained efforts by EPA's international activities office that we have had a role in the non-proliferation area. We have also experienced problems regarding international activities in the nuclear area as conducted by the International Atomic Energy Agency. In the past, State and DOE have failed to notify EPA on a timely basis when EPA personnel have been requested to serve as technical experts to IAEA committees and/or working groups. This is particularly troublesome in those areas where EPA has regulatory responsibilities such as ocean dumping of radioactive waste.

Question. In his testimony, Dr. Rowe noted that several agencies had refused to participate with EPA and that he knew of no way to force them to cooperate. What reasons did these agencies give for not cooperating? Do you see this inability to force participation as a major problem for EPA? Does EPA have any alternatives in this situation?

Answer. Two agencies have chosen not to be represented on interagency working groups developing Federal Guides under the former FRC authority; DHEW on diagnostic x-rays in the healing arts, and DHEW and DoL (OSHA) on updated Federal Guides for radiation workers. The primary reason for these actions was a question of overlapping authority with these agencies. EPA, however, has continued its efforts in these areas with representatives from other agencies involved. We have benefited from technical advice received from staff of DHEW. We believe we can, through a spirit of cooperation and showing mutual respect for each agency's responsibilities, resolve our differences on issues of "turf". This is exemplified by the Memorandum of Understanding which EPA and DHEW have signed relative to radiation protection in the healing arts.

Question. During a discussion of the misunderstanding related to the detection of radiation from China's nuclear tests of Sept. 1976, Dr. Rowe mentioned that all of the relevant agencies have now agreed on a prototype operating plan. Presumably, this plan defines the procedures for dealing with such situations in the future. Could you give us a description of this plan and indicate which agencies are involved?

Answer. A Memorandum of Understanding (MOU) is being developed to designate the roles of Federal agencies in responding to incidents of atmospheric detonation of nuclear devices. This MOU is divided into two parts. The first deals with the movement of contaminated air masses over the United States and possible effects at ground level due to dry fallout or rainout of radioactive debris. The second part is concerned with commercial aircraft flights which may pass through the contaminated air masses at various altitudes.

The primary responsibilities identified in the MOU include:

(1) Notification that a nuclear detonation has occurred, (time, yield, altitude). (All Agencies)

(2) Locating the contaminated air masses and forecasts of time of arrival, path over the United States, and areas of potential rainout. (DOD, NOAA)

(3) Activation of monitoring programs. (EPA, FDA)

(4) Exchange of data. (All Agencies)

(5) Assessment of radiation exposures. (EPA)

(6) Advice on surveillance and protective action guides. (EPA)

(7) Precautions for air commerce. (DOT–FAA)

(8) Press releases and other communications. (All Agencies)

The agencies to sign the MOU include: EPA, DOE, NOAA, NRC, FDA, DOT(FAA), DOD. In addition, an appendix to the MOU will identify individuals responsible as contacts for implementing the MOU, along with pertinent phone numbers which will be updated every six months.

Senator STEVENSON. The hearing is adjourned.

[Whereupon, at 1 p.m., the hearing was adjourned, to reconvene at 10 a.m., Friday, June 17, 1977.]

RADIATION HEALTH AND SAFETY

FRIDAY, JUNE 17, 1977

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, D.C.

The committee met at 10:05 a.m. in room 5110, Dirksen Senate Office Building; Hon. Adlai E. Stevenson presiding.

Senator STEVENSON. This morning the Committee on Commerce, Science, and Transportation begins the second day of a 5-day series of hearings on health and safety effects of ionizing and nonionizing radiation.

Yesterday we heard from Federal agencies which play major roles in radiation protection: the Bureau of Radiological Health within the Food and Drug Administration, and the Environmental Protection Agency.

Today we will hear witnesses from the private sector who are closely involved with the Federal radiation protection programs. We want their candid assessment of the problem and the adequacy of Federal research and regulation.

Our first witness is Rose Kushner, the executive director of the Breast Cancer Advisory Center in Kensington, Md.

Thank you for joining us this morning.

We would be happy to enter your full statement in the record if you would like to summarize it. If not, we would be happy to hear the full statement.

STATEMENT OF ROSE KUSHNER, EXECUTIVE DIRECTOR, BREAST CANCER ADVISORY CENTER, KENSINGTON, MD.

Ms. KUSHNER. Thank you.

My name is Rose Kushner. I am the executive director of the Breast Cancer Advisory Center, and I am also the author of a book entitled "Breast Cancer: A Personal History and an Investigative Report." I am also a breast cancer patient. So I speak to you today from several points of view.

My testimony concerns mammography—X-rays of the breasts to detect early breast cancer—a subject of much fear and confusion among women today.

Before going further, I must make a clear distinction between "screening" by mammography and "diagnostic" mammography. The controversial issue is whether anyone should be taking routine, periodic X-rays of healthy women who have no reason to think they have a higher than the normal 7-percent risk—in the United States—of developing breast cancer.

Diagnostic mammography is necessary when a woman has a possible symptom of the disease, and there is no controversy about using this kind of X-ray. When a sign of breast cancer is present, the risk that something is wrong by far outweighs any fear that the radiation may cause or accelerate something that will show up years later.

Therefore, what I am about to say refers only to periodic, routine screening of asymptomatic women.

Breast cancer is the No. 1 killer of women between the ages of 44 and 55 in the United States. It need not be. If the disease is discovered early, before it has spread—or metastisized—to other parts of the body, it may be cured by surgery. Unfortunately, because of the biological nature of cancer—especially insidious in the breast—the disease is usually not detected in this early, curable stage. Except for special circumstances, early breast cancer does not hurt; it does not cause any change of appearance or size; it cannot be felt. A single malignant breast cancer cell can take as long as 9 years to grow to the size of a pea.

For these reasons, women were rarely diagnosed early enough to have the disease confined to the breast itself. More than three-fourths of all women undergoing surgery were found to have metastatic spread to the lymph nodes or glands of the underarm area, the axilla.

The use of diagnostic mammography began in 1960. Even though early techniques and equipment were crude and unsophisticated by today's standards, it soon became apparent that breast X-rays had the capability of detecting cancer while the tumor was still in its preclinical microscopic stage.

In 1963, the Health Insurance Plan of Greater New York—HIP—began a comparative study to see if mammography actually lengthened women's lives.

Two groups of women were chosen for the trials. The study group was given mammography in addition to the regular HIP annual physical examination; the control group received every other test and examination except the breast X-rays. After 7 years of screening, HIP statisticians found that, of the women who were mammographed, only 70 had died of breast cancer. Of the women who were omitted from the X-ray screening, 108 were dead of the disease.

Because of the impressive statistics of the HIP trials, the American Cancer Society and the National Cancer Institute joined in 1973 to cosponsor 27 breast cancer detection demonstration projects. Their purpose was to conduct annual screenings of about 270,000 women in cities all over the United States.

Each screening session was to include a thorough physical examination of the breast, mammography and thermography—a detection technique that relies on photographing heat retention patterns of the breast.

Women were self-selected, that is, they volunteered to be part of the program and were not chosen at random as the HIP participants were. The lower age limit was 35 rather than 40, and there was no maximum age—subsequently changed to 74.

By the time the recruitment was completed, 260,281 women had entered the screening programs.

At the beginning, the detection centers did not receive much general publicity but this situation changed dramatically in the fall of 1974 when Mrs. Betty Ford and Mrs. Happy Rockefeller underwent their mastectomies. Suddenly, all the media ballyhooed the existence of mammography and showed photographs and films of women having this pain free test. As is too frequently the case, claims were made that exaggerated the reliability of the technique. Some examples of the articles are attached to my statement. Within a matter of weeks, women all over the country were inundated with information about this lifesaving machine, and waiting lists for mammograms were often months long.

Omitted from this flood of media coverage, however, was the behind-the-scenes conflict among scientists about the potential danger of exposing healthy breasts to a known carcinogen, X-ray. It has been known since the days of Madame Curie that radiation causes cancer, and that its effects are cumulative; that is, its cancer-causing power is not excreted or absorbed, but is built up over the years of exposure.

Breast cancer experts also knew that relatively large doses of X-ray were required to penetrate the soft tissue of the breast and that these organs are very vulnerable to any carcinogen. Essentially, opponents of routine screening by mammography argued that radiation may actually cause cancers to be triggered, and that the risks of mammography outweighed the benefits in large populations of women.

However, none of us women knew anything about the controversy that was swirling around our breasts as we waited, blissfully ignorant, to have our mammograms taken.

True, in January 1976, Dr. John C. Bailar III, editor of the Journal of the National Cancer Institute, published his view that the HIP study had not shown any increase in survival rates among the women under age 50. The women who appeared to have benefited from the early detection X-rays were the older group. Therefore, he wrote, younger women were being exposed to potentially dangerous X-rays for as long as 15 years for no reason at all.

This was the first public—if you consider anything printed in a medical journal to be "public"—surfacing of the controversy. Dr. Bailar's paper received slight mention in the lay media but not enough to alert us women. However, it did convince Dr. Frank J. Rauscher, Jr., the former Director of the National Cancer Institute, to appoint a committee to analyze the HIP data and see if mammography did harm or good.

Dr. Lester Breslow, a distinguished epidemiologist from UCLA, studied the statistical aspects of the HIP trials, and Dr. Arthur C. Upton, an expert in radiobiology from the Brookhaven National Laboratory, extrapolated from data regarding breast cancer incidence among three groups of women: Survivors of the atomic bomb raids in 1945, women who had been X-rayed frequently to monitor tuberculosis, and young women who had been X-rayed for chronic mastitis—a benign breast disorder that frequently follows pregnancy. Dr. Louis B. Thomas, the NCI's Chief of Pathology, had the job of reviewing all the cancers and suspected cancers found in the HIP study. Because this third part of the three-pronged evaluation required more time, the Breslow and Upton reports were submitted earlier, in July 1976.

Dr. Upton found that there was indeed an increased risk, theoretically, of developing breast cancer after repeated exposure to X-ray. While this risk was small per year, it was cumulative, and the 15 years of exposure between age 35 and age 50 did not appear to be justified since there was no increase in the younger women's survival rates. The reasons for this phenomenon are, I gather, due primarily to the fact that the breast tissue of younger women is such that X-rays are incapable of distinguishing their inner aspects as well as they can in the breasts of older women. Dr. Breslow's statistical analysis reinforced the view that women under the age of 50 had not benefited from mammography in the HIP study.

This open meeting received a great deal of publicity as did a later meeting of NCI's female employees. Only then did women in the United States get the warning that the miracle of mammography might be a double-edged sword. As a result, thousands of women below and, unfortunately, above the age of 50 dropped out of the NCI–ACS screening programs.

On the official level, the NCI sent out a "Dear Doctor" letter dated August 23, 1976, describing interim guidelines. This letter—signed by Dr. Diane Fink, Director of the Division of Cancer Control and Rehabilitation, and Dr. Arthur I. Holleb, senior vice president for medical affairs of the American Cancer Society—restricted routine mammography in the 27 detection centers for women over age 50. However, if younger women and their physicians felt the X-ray examination was warranted because they had a higher than normal risk of developing the disease, this would be allowed.

Such high-risk women include those who, like me, have already had the disease in one breast; those who have a strong family history of breast cancer; women who have a history of benign breast disease and those who are chronically cystic and repeatedly develop breast masses.

These interim guidelines applied only to the 27 NCI-ACS breast cancer detection demonstration projects whose equipment was to be stringently monitored by physicists and which were operated by certified radiation technologists.

According to the Bureau of Radiological Health, there are between 5,000 to 6,000 mammography machines being used in the United States today. Using the minimum figure as a base, this means that the NCI guidelines did not affect the other 4,973 pieces of apparatus in doctors' offices, hospitals, clinics, et cetera. Thus, millions of women in the United States were not protected by the "Dear Doctor" letter of August 23, 1976. However, this time there had been enough media exposure and publicity to warn women of the possible dangers of routine screening. We became very cautious about having our breasts X-rayed.

As a medical reporter with a personal, as well as professional, interest in the fracas, I had attended many of the meetings and conferences.

I became curious about the nonrole being played by the Bureau of Radiological Health, supposedly our watchdog agency over the medical applications of radiation.

Where was the BRH in this argument? Why weren't the Bureau's opinions and/or recommendations included in all the discussions? Wasn't it doing anything about the mammography controversy?

A day at the headquarters of the Bureau of Radiological Health in Rockville gave me some answers. Yes, the BRH was trying to inject its learned and tax-supported opinions into the controversy. But no one seemed to be listening.

For example, although advocates of mammography were insisting that the 1 rad absorbed by a breast from mammography was not dangerous, Ronald C. Jans, a BRH physicist, had published a paper reporting a survey of random medical facilities in Pennsylvania and in the District of Columbia. These included hospitals, private radiologists' offices, and clinics. According to this survey, the radiation dosages emitted by the equipment ranged as high as 47 roentgens per exposure.

At this point, I would like to insert the distiction betwen the rad—the unit of radiation measurement we women have learned about—and a roentgen, a word seldom mentioned to us. A rad measures the quantity of radiation absorbed by any tissue. In the case of the breast, rads are counted at midpoint in the organ. A roentgen, on the other hand, is the quantity of radiation emitted by a particular piece of equipment.

Thus, there is absolutely no way for any women to know, or for any physician or technician to be able to tell her, precisely how many rads her breast is absorbing. Obviously, this can only be estimated and will vary according to the size and density of her breast.

However, it is possible to compute the number of roentgens a woman's breast is receiving. In general, physicists estimate that women with medium-density, medium-sized breasts absorb about 20–25 percent of the roentgens to which they are exposed.

Using the data from the Jans paper, then, some women were absorbing about 10 rads per exposure, a dosage far exceeding the recommendations of mammography's most vocal supporters.

And, while the NCI–ACS projects were staffed by certified technologists who were able to get good films with two exposures per breast, out in the "real world," women were often mammographed X–ray technicians who had minimal training and had passed no qualifying examinations. In these cases, more than the two exposures per breast were often required in order to have good enough images for a radiologist to interpret.

It goes without saying that in addition to having good equipment and trained personnel, women also depend on having competent, well-trained radiologists who know what they are looking for and how to tell the difference between something that is normal and something that is not.

Women participating in the NCI–ACS detection centers are more likely to have topnotch equipment, technologists, and radiologists than the rest of us are.

As a result of the Jans paper, the Bureau of Radiological Health began a mammography quality assurance program to be known later as BENT. However, I learned that there is nothing the BRH can do to force radiologists to participate. There are no laws that require radiologists to accept the free monitoring service offered by the Bureau. Indeed, the BRH has no legal authority at all once radiation equipment is installed in the place where it is to be used. The Bureau can and does inspect (and reject) equipment in the plant where it is manufactured. It also inspects the apparatus when it is installed to be sure that this is properly done.

However, the Bureau's powers end at this point, because there are no Federal laws enabling it to regulate usage. It is up to the individual States to see to it that the equipment is checked periodically, that it is well calibrated, does not leak, exposes all patients to the minimum quantity of radiation required for maximum resolution, and that the technologists using the equipment know what they are doing. Most States' regulations vary from awful to mediocre.

In all of the brouhaha surrounding the mammography controversy, the importance of the radiation technologist has been ignored. Only three[1] States of the 54 entities—including the District of Columbia Puerto Rico, Virgin Islands, and Guam—of the United States have licensure requirements for these important professionals.

To explain how vital the neglected technologist is, I would like to use an analogy with photography. The mammograph is the camera, either a Leica or a Brownie Instamatic. In photography, the energy is light, and in mammography, it is X-ray. A camera's film can be Tri-X and very fast, like low-dose mammography film; or slow, like high-dose, requiring a great deal of energy to take a picture. The radiologist is the counterpart of an art critic who comes in and views the picture for its merit. The crucial person in the whole process is, of course, the photographer or the radiation technologist.

If, for example, I had a Leica, a sunny day and the best of film, any photograph I took with it would probably not be as good as one taken by Eisenstadt with a Brownie and slow film. Yet, the Bureau of Radiological Health has absolutely no jurisdiction over the qualifications of these professionals. Only three States have any at all.

So this is what I learned from our watch-dog agency; once a piece of mammographic equipment is installed and inspected, the Bureau has no power over its continuing usage. It may only suggest guidelines and make recommendations.

Our watchdog has no teeth.

In the meantime, the mammography controversy—minus input from the Bureau of Radiological Health—was, and is still, raging. Although the August 1976 interim guidelines were still in effect over the 27 NCI–ACS detection centers, only a fraction of U.S. women are covered by these. What is done to the rest of us is governed by recommendations from the American College of Radiology, the American Cancer Society, the American Medical Association, and a mixed bag of agencies, public and private, all of whom have their conflicting opinions presented to women by way of the print and electronic media. Manufacturers of the products involved produced low-dose film and other technical changes that enabled mammograms to be taken with smaller quantities of radiation, and these firms promote mammography as well.

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[1] Mr. Villforth indicated 5 States had instituted licensing programs.

In addition to these groups, the EPA is also in the act, because it has jurisdiction over equipment used in Federal facilities. Even NASA has entered the mammography controversy by developing a computerized enhancement gadget transferred from space-age technology.

Various "authorities" are playing on the various factors that make a woman "high risk," and they have published lists of indicators—including fear of cancer—that, if valid, would mean 80 percent of all American women are in danger of developing breast cancer. Since the national incidence rate is only 7 percent, this is patently absurd.

The result of this controversy has been a reign of terror compounded by confusion. As the director of the Breast Cancer Advisory Center, I get instant feedback from women who don't know what to do. The situation is in a grand state of mess.

As I mentioned earlier, one of the grave dangers has been that women who are at high risk of developing breast cancer have refused mammography. I know of at least five women who have already had a mastectomy but who will not permit their physicians to X-ray their remaining breast. I had hope that the completion of the Thomas section (on pathology) of the NCI's evaluation would resolve the problem once and for all.

This important study was finally released at the end of March 1977 and was supposed to be the definitive statement regarding the value of mammography. Combined with the earlier reports by Drs. Breslow and Upton, the pathologists' analyses of the slides from the HIP trials showed that the cancers found by mammography only where (1) sometimes large enough—2 cm in size—to have been found by a thorough physical examination, and (2) 17 of the 44 malignancies were microscopic in situ cancers that might never have grown large enough to be felt had the women not been diagnosed by mammography.

The unanimous recommendation of the three ad hoc working groups was, therefore, that the screening of women under 50 by mammography be stopped immediately. Moreover, even in women over 50, there was no conclusive evidence of benefit. Therefore, they suggested that "further National Cancer Institute support of mammography in breast-cancer screening of women over 50 * * * be concentrated on validating its use through appropriately designed randomized clinical trials."

However, rather than ending the controversy, these reports merely added fuel to the fire. Now, still another group of committees headed by Dr. Oliver Beahrs of the Mayo Clinic, is in the process of doing the same kind of analyses of the detection centers as the earlier committees did of the HIP trials.

In the meantime, the NCI issued new interim guidelines on May 9, 1977—these unilateral, without the cosupport of the American Cancer Society—restricting screening by mammography of women under age 50 only to those who have had breast cancer themselves or whose close relatives have had the disease.

This, again, applies only to the 27 detection centers and has no effect on the other thousands of mammography clinics.

Dr. Diane Fink, with the approval of the advisory board to the Division of Cancer Control of the NCI, set these tight limitations because a report from the centers had shown that from 29 to 100 percent of women under age 50 were still being screened routinely in spite of the August 1976 interim guidelines.

The advisory board felt that these percentages exceeded any estimates of the number of women who could be considered "high risk." Everyone is now waiting for the Beahrs report which is expected in September 1977.

So we women are still waiting for the experts to help us make our decisions. Because I am in a position to know more about what is going on than most women. I am afraid that the Beahrs report will still not settle the controversy for us.

For one thing, whatever the NCI may pronounce will apply only to the women who are currently participating in the 27 centers, leaving millions of the rest of the female population of this country in the care of physicians who may or may not know their trades, poorly trained and unqualified technologists and unmonitored equipment of unknown vintage.

My worries can be best explained, I think, by listing the questions that will still be unanswered by the Beahrs report:

1. If the U.S. Bureau of Standards has the authority to inspect weights and measures in grocery stores and butcher shops all over the United States, why does the Bureau of Radiological Health not have the power to go into a radiologist's office to check the equipment that exposes our breasts or a man's testicles to carcinogenic irradiation?
2. Why are there not Federal laws requiring that all X-ray technologists pass qualifying examinations, repeated every 5 years or so, so that we can be sure the person pushing the button knows what button to push?
3. With all the talk of new films that require less and less radiation for a good image, how can we women be sure that the reduced radiation level is not so low that it misses a cancer entirely? After all, a "false negative" today—as mine was—is far more dangerous than worrying about triggering a cancer that will appear in 15 or 20 years.
4. If mammography is unreliable in younger women because of the anatomy and physiology of their breast tissue, why expose them to any risk at all, however minute this risk may be?
5. In view of the HIP trials where 17 of the 44 cancers found by mammography were microscopic in situ cancers, is it possible that X-rays are finding cancers that might be stopped or even destroyed by the body's immune system if a mastectomy were not done?

I would like to pause here to tell the committee that in one detection center I visited, the prevalence rate—that is, the number of suspicious mammograms reported—was 10 times the U.S. breast cancer incidence rate. Of course, the whole point of screening is early detection, and it was expected that the first few years of screening would exceed average U.S. incidence rates. But a factor of 10 is beyond belief! The mammograph must be picking up lesions that would never have grown had they not been discovered microscopically.

Of course, these "lucky" women are cured and will not die of breast cancer. But they might have lost their breasts for nothing.

6. I would also like to talk about money. In the Washington area, a set of mammograms now cost more than $50, in addition to the physician's fee for a physical examination of the breasts. No one I have discussed cost with can account for this unreasonable expense, and I think the radiologists are ripping women off. A radiologist from the Karolinska Institute in Sweden told me that a mammographic examination costs only $5 there. Taking into account the Swedish Government's subsidization of medicine, this still means that $25 would be a healthy fee for mammography in this country.

The difference in cost, I am afraid, is nothing more than financial exploitation of women's terror.

To sum up, I would like to tell members of this committee that American women are completely bewildered and afraid. I think the time has come when private agencies and the media should get out of the mammography controversy entirely and let all our expensive, tax-supported scientists in all related agencies get their heads together and formulate rules and regulations—not guidelines and recommendations—to protect us.

It is outrageous that the baker whose scales give us 14 ounces of bread instead of a full pound is penalized when the radiologist whose mammograph gives us overexposure to irradiation is not. It is outrageous that the beautician who shampoos, cuts, and sets our hair must pass difficult qualifying examinations and be licensed when X-ray technicians are not required to do so.

The medical aspects of the mammography controversy are issues that the Congress of the United States cannot be expected to resolve. However, we taxpayers do have the right to demand that our legislators do what needs to be done to regulate the personnel and the equipment so that our health, and perhaps even our lives, will be protected.

And I submit the addenda.

Senator STEVENSON. Thank you, Ms. Kushner.

The attachments to your statement will be entered in our record. You say that only three States now license the technicians?

Ms. KUSHNER. Yes. New York, New Jersey, and California.

Senator STEVENSON. Is there a movement underway within the States to extend this?

Ms. KUSHNER. Seven States are attempting reforms of one kind or another.

Senator STEVENSON. Do the States do an adequate job, in your opinion, of inspecting the equipment?

Ms. KUSHNER. According to what I have been told, some States are quite good. New York is quite good. Maryland—I was particularly interested because it's my home State—is considered mediocre. And there is a great shortage of personnel. Regulating radiation involves equipment, it involves the inspection of radium mines in Wyoming. It involves all kinds of X-ray equipment. And I'm told that they are grossly understaffed. Certainly on the Federal level they are understaffed. I have not gone into each State to check. I only know what I'm told.

Senator STEVENSON. What do you suggest we do? The Federal Government does not license nurses and does not license doctors.

Are you suggesting that the Federal Government ought to license the technicians?

Ms. KUSHNER. I certainly think the Federal Government has the power to give the Bureau of Radiological Health the power to inspect usage, and to do whatever needs to be done to enable the Bureau to do that. As I said in my testimony, it's kind of silly that scales are monitored and that beauty shops are monitored by different health agencies every month in Maryland, but the average doctor's X-ray machine is inspected only about every 3 years.

Senator STEVENSON. That's not enough; is it? Even if the agency was to randomly and periodically inspect the equipment, and that's being done to some extent now by the States, and second, isn't the larger concern the use of that equipment?

Ms. KUSHNER. Inspecting the usage of the equipment is most important. For example, there is a certain amount of leakage that must be checked. Now, the BENT program involves attaching a specially impregnated disc to the machine. It's no big deal. A disc is attached to the machine and then the doctors mail it in. The Bureau can then tell if the machines are overexposing, underexposing, if they are doing what they are supposed to do. BENT is a no-cost program. Doctors don't even have to put a stamp on the envelope. I think that the dental program—DENT—has been in effect for about 5 years, and the Bureau has about 30 States cooperating in the whole country. My dentist, for example, just started participating because one of his technicians got pregnant. He was afraid he might do her some harm.

Senator STEVENSON. Is there a level of exposure expressed in roentgens that's regarded as acceptable? You mentioned dosage as high as 47 roentgens.

Ms. KUSHNER. Yes; but I understand that situation has been fixed, and it's no longer that high. But the mean was 24 roentgens, which would be 5 rads per exposure. Breast experts have stated that an exposure maximum of 1 rad—4 or 5 roentgens—should be the goal of all radiologists. I understand that this is the case in the 27 NCI-ACS detection centers. I had nine exposures of unknown quantities of X-ray, because the technologists kept doing the films over. I didn't know any better then. The technicians didn't known the roentgens, either. The numbers have to be computed from KVP and MAS in order to give you the number of roentgens. She didn't know the roentgens, or he—some technicans are men. I imagine the radiologist probably knows; I don't know. This is the problem; there are too many "I don't knows" about this.

The average X-ray technician in the State of Maryland doesn't need to pass any test. I answered three blind ads in the paper and all I was asked was what salary I wanted.

Senator STEVENSON. All you were asked was what?

Ms. KUSHNER. What salary I wanted. It's scary.

Senator STEVENSON. Do you have any figures as to what percentage of women are treated by the detection centers, as opposed to other places?

Ms. KUSHNER. I have the precise number that were enrolled. Many of them had dropped out. But as of the end of December, before all of this started, there were 260,281 women—roughly half above and half below the age of 50. Fifty is an arbitrary number that was chosen, but it should be the age of menopause. The HIP study chose 50, and so that number was continued. My mammogram was a false negative, for example. I am under 50. It said I had nothing. I'm glad I didn't listen to that diagnosis. Mammography is not very reliable under age 50.

Senator STEVENSON. So it's not just the exposure, but above 50 it's more reliable, too?

Ms. KUSHNER. Yes. As you get older, you sort of drop a little.

Senator SCHMITT. I'm just getting exposed to this whole subject. The one concern I would have is the size of any additional Federal bureaucracy that might need to be established to do this, and whether you could get the qualified people to do these things. I guess that's the major reason we're having these hearings, to try to understand it.

Ms. KUSHNER. I think it's kind of strange that EPA should be issuing its own guidelines, and I have a copy of its Federal Register publication,[1] and that the Bureau of Radiological Health should be doing its guidelines. Why don't they get together? And now NASA has confused the issue more.

Senator SCHMITT. That's a good point. I think we need to answer these questions. But if you're talking about a Federal program to not only inspect all of the X-ray equipment in this country, but also license the people operating that equipment, you're talking about a major effort. That might be what the country should do. But we should not do it without examining the scope of that effort. It's not going to be 180 employees. It's going to require a large number of people.

Ms. KUSHNER. There are a lot of things at stake here, though.

Senator SCHMITT. Well, I agree with you. But there are a lot of things at stake all over this country. It's really a question of priorities.

Ms. KUSHNER. This has higher priority than the Bureau of Standards inspecting the scales, I think. That's only money. This is lives we're talking about. If you have got to cancel one instead of the other, get rid of the inspection of scales.

Senator SCHMITT. I have a feeling the Federal Government will not be able to accomplish all the things it will be asked to do in this area. I'm not arguing with you about the importance of this evidence. I'm just saying that it's not something that can be established instantaneously without considerable analysis of the impact on you, the taxpayers and everybody else.

Ms. KUSHNER. I appreciate that. But we have got to start somewhere.

Senator SCHMITT. And we have.

I appreciate very much your testimony. We'll continue to evaluate it in the light of other things that we do.

Ms. KUSHNER. Thank you.

Senator SCHMITT. Mr. Chairman, if I could just interject a point that has nothing to do with this subject, just for the people that are present here. Wernher Von Braun has died. I would like to say that all of us who were associated with him feel a great loss. This committee, with jurisdiction over the aspects of space and space science, I think, will also feel the impact of that loss. Thank you.

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[1] See Federal Register, vol. 42, No. 17—Wednesday, Jan. 26, 1977, p. 4884.

Senator STEVENSON. Thank you, Senator Schmitt. Ms. Kushner, did you hear the testimony yesterday?

Ms. KUSHNER. No; I did not. I was not able to be here. Mr. Villforth spoke.

Senator STEVENSON. The FDA indicated that between 30 and 50 percent of the new X-ray equipment being sold did not meet its standards. That's new equipment.

Ms. KUSHNER. But the Bureau of Radiological Health is empowered to require the manufacturer to do whatever needs to be done in the plant before the equipment is shipped. The Bureau has the power to do this.

Senator STEVENSON. They have that authority. But it's between 30 and 50 percent of the new equipment, newly designed, and currently being sold which is not in compliance with their standards; that fact makes you wonder about the equipment that's out there already. And as you have indicated, the old equipment is only part of the problem. At least the States, though the record is uneven, have the authority, and to some extent are inspecting the equipment. But if 30 to 50 percent new equipment is not meeting the standards, surely the old equipment is even worse. Then there is the additional problem with the users of the equipment, and there you have only a few States licensing the technicians.

Well, I don't know what the answer is, either. But I certainly agree that something must be done. And if not by Federal regulations, perhaps, by or with some Federal encouragement. With some minimum standards, perhaps the States would be moved to do a job of inspecting the equipment and licensing technicians.

Ms. KUSHNER. Well, in terms of—I'm just throwing this out—but can the Federal Government do something because of medicaid and medicare?

Senator STEVENSON. Yes: legislation has been introduced. You may be familiar with Senator Randolph's bill to establish Federal standards for licensure.

Ms. KUSHNER. I think that would be a lever to get into the States' territory.

Senator STEVENSON. Excuse me?

Ms. KUSHNER. Wouldn't that be a lever for these institutions because they have to have inspected equipment for women over 65 because they are on medicare? They are going to use the same equipment for the rest of us and this would protect women under age 65.

Senator SCHMITT. The medicaid and medicare lever is being used in numerous circumstances, and is one of the major problems that many individuals in the States are having with the Federal Government right now. In this area I think certainly a first step should be to encourage the States and medical and related associations to establish standards on their own. I certainly hope these hearings will encourage such standards. Without them, I think that eventually the Federal Government will get involved, regardless of the results of this hearing and Senator Randolph's bill.

Senator STEVENSON. Thank you, Ms. Kushner, for your testimony. It has been very helpful.

[The attachments referred to follow:]

[From the New York Times, Friday, Nov. 7, 1975]

BREAST CANCER PROJECT CALLED SUCCESS

(By Jane E. Brody)

Four out of five women whose breast cancers were detected through a nationwide screening project were found to have an early stage of disease with a very high chance of being cured, according to a progress report issued yesteday.

This is twice the percentage of breast cancer patients who are ordinarily found at the time of surgery to have potentially curable cancers.

The project which thus far has data on 165,000 women screened once and 58,000 screened more than once, is aimed at determining if organized detection programs can make a dent in the breast cancer mortality rate, which has not changed significantly in the last four decades.

LEADING KILLER OF WOMEN

Breast cancer is the leading cancer killer of American women and the leading cause of death among women aged 40 through 44. It will be diagnosed in an estimated 89,000 women and will cause 33,000 deaths this year.

When cancer is detected and treated while still confined to the breast, 85 to 99 percent of women can expect to be alive and well five years later. But if the disease has already spread to one or more lymph modes surrounding the breast, only 45 percent survive five years.

There are now 27 demonstration centers around the country, under the sponsorship of the National Cancer Institute and the American Cancer Society, that are using three detection methods to examine healthy women for hidden signs of breast cancer. Manual examination by a physician or trained nurse, mammography, a special breast X-ray, and thermography, a heat-sensitive picture of the breast.

REDUCED SURGERY EXPECTED

At a news conference here yesterday held by the American Cancer Society and the American College of Radiology, doctors said that they fully expected the screening to lower the breast cancer death rate and to reduce the need for extensive surgery to cure the disease.

Dr. Robert Hutter, chairman of pathology at St. Barnabas Hospital in Livingston, N.J., said that the screening program was picking up many cancers before they were even lumps—while they were still microscopic islands of cancer cells.

At his hospital, he said, such early cancers are usually treated by removing the underlying tissue of both breasts but leaving the outer skin and nipple intact. The breasts are artificially reconstructed at the same time.

Cosmetically, Dr. Hutter said, this gives a better result than standard breast surgery, which involves removal of the entire breast and surrounding lymph nodes.

"It is also psychologically less traumatic since the woman awakens from anesthesia with two breasts that look much like the ones she had when she went under," he added.

He emphasized, however, that most surgeons had not yet adopted this approach to the treatment of very early breast cancers.

SCREENING PROGRAMS ATTACHED

Recently, some doctors have criticized breast cancer screening programs, charging that repeated X-ray examinations of the breast will eventually cause a large number of cancers because of the radiation exposure involved.

Dr. H. Rodney Withers, radiotherapist at the M.D. Anderson Hospital and Tumor Institute in Houston, said that the low-dose X-ray examination of the breast could be expected to result in some 15 or more years later in at most 20 cases of cancer per one million women screened each year.

On the basis of the first year's screening results, he estimated that 2,500 of one million women screened would be found to have early curable cancer. This would give a "benefit-to-risk ratio of 125 to 1," Dr. Withers concluded.

In the second and subsequent years of screening, the detection rate is expected to drop by a factor of about three, but even then the benefit-to-risk ratio would be about 40 to 1 he added.

"Thus, screening confers a relatively low risk compared to the risk a woman faces of developing breast cancer," Dr. Withers said. One in every 15 American women can be expected to develop breast cancer sometime during her lifetime.

Some of the women whose detection examination led to a recommendation that the breast be biopsied for possible cancer have not had the biopsy either because they had refused to have it done or because their doctors distrusted the results of the examination because they could not feel a tumor.

Dr. Benjamin F. Byrd, president of the cancer society and surgeon at Vanderbilt University in Nashville, said that part of the screening program involved patient and physician education and that every biopsy recommendation would be pursued until all involved understood its implications.

[From the New York Times, July 20, 1976]

BENEFITS STUDIED FOR CANCER TESTS

BLUE CROSS, SEEKING EARLY SCREENING, CONTRACTORS FOR U.S.-AIDED RESEARCH

(By Lawrence K. Altman)

The Blue Cross Association said yesterday that the "recent sharply rising cancer death rate" in this country and rising costs of health care had spurred it to take a first step toward providing coverage for screening tests to diagnose malignant tumors at an earlier stage among its nearly 90 million subscribers.

Blue Cross officials said they had contracted with the National Cancer Institute, a Federal agency, to undertake a study, covering several years, of the various factors that would be involved in offering such a screening program as a prepaid health care benefit.

The program is aimed at detecting more cancers in the silent phase, before they have produced symptoms. Cancer is the country's second leading cause of death behind heart disease, and Blue Cross officials said they believed that many lives could be extended by earlier detection of cancer.

Walter J. McNerney, the Blue Cross Association president, said, "The study will determine whether the early detection and treatment of cancer would lead to improved survival rates and lower treatment costs and, if so, whether it would be economically feasible to offer the new benefit on a nationwide scale."

In the first year of the study, which is scheduled to begin August 1, Blue Cross and National Cancer Institute staff members will try to determine which types of cancer before symptoms develop. There are scores of different malignant tumors, all of which are categorized as cancer. Their detection depends on a wide variety of factors such as location in the body, age, sex and family history of cancer.

Blue Cross officials said that the association did not know the specific types of screening tests that would prove worthwhile on a cost-effective basis for large population groups.

Among the ideas to be considered for study are the use of paramedical workers to do rectal examinations to detect bowl and prostate cancers; mobile vans to bring X-ray machines to the work-site to do mammograms to detect breast cancer in women, and educational programs.

Blue Cross officials said they recognized that the program could lead to controversies over the use of nonphysicians, the choice of screening test, and choice of institution in a community where the tests would be offered.

AFTER DIAGNOSIS

Blue Cross currently covers the costs of treatment when cancer in diagnosed after suspicious symptoms have developed. Often such symptoms are discovered by the patient through such guidelines as the American Cancer Society's "Seven early warning signals," and through regular physical examinations in a doctor's office.

However, Blue Cross officials pointed out that self-discovery was not completely effective because cancer is often caught after it has already spread, reducing the patient's chances for survival.

Further, Mr. McNerny said, "The healthy person, free of any symptoms, often omits such routine cancer checkups because testing costs are not regularly covered by health insurance or prepayment programs."

One aim of the study is to determine whether death and sickness rates can be reduced when the financial barrier is removed and Blue Cross pays for testing before symptoms occur.

Most health officials have maintained that because of cancer's complexity, early detection through screening is becoming increasingly important as the best means to reduce cancer death rates. But, as Blue Cross said, the traditional modes of screening have generated costs that are considered too high for coverage by health insurers and other third-party payers.

Accordingly, the study is aimed at seeking answers to such questions as the following:

How will the cost of treatment and the decrease in deaths from cancer for patents being screened compare with the costs of cancer treatment without early screening?

Will savings, if gained, balance the cost of administering the program and providing the benefit?

Which facilities should be used to make screening available to the large proportion of the population to be covered—hospital-based outpatient clinics, health maintenance organizations, industrial clinics, free-standing clinics, mobile or outreach clinics, or others?

What educational programs will be necessary to encourage the public to use early screening when cancer can be discovered soon enough to minimize early treatment?

[From The Milwaukee Journal]

THIS PROJECT'S A LIFE SAVER

(By Constance Daniell)

The technician opened the door as I was interviewing Dr. John W. Milbrath, coordinator of the Breast Screening Project at Milwaukee County General Hospital. An hour earlier I had gone through the free screening process myself; now Dr. Milbrath was giving me the story on the project which at that time had been in operation a little more than eight months.

Would I stay for a few minutes after the interview? the technician asked. She had felt "something suspicious" during the physical examination, and wanted the surgeon to see me.

By that morning in mid-March 3,000 women had been examined in the project and figures had been tabulated on 2,500.

THE BREAKDOWN

Of that number, 65 were regarded as suspicious. Thirty-seven of the suspicious cases proved to be benign tumors; 15 were unproven and would be carefully watched and re-examined at regular intervals, and 13 were operated on for cancer.

I had not the slightest premonition that the odds were due to change slightly. I was to become No. 14 in the mastectomy column.

[As of this week 3,400 women have been screened, which brings the total of suspicious cases to 84. Of those, 50 tumors were benign; 18 are unproven and 16 were operated on for cancer.]

The examination at the Breast Screening Project is a three part process. There is the conventional physical examination of the breasts followed by xeromammography and thermography, two highly sophisticated methods for detecting breast cancer that have been available for medical use since about 1971, Dr. Milbrath said.

Director of the project is Dr. James Youker, chairman of the Department of Radiology at the Medical College of Wisconsin and the hospital.

The tests are conducted by three radiology technicians who have graduated from a two-year course at Wilwaukee County General. The technicians have been specially trained in the screening process by Dr. J. David Lewis, assistant professor of surgery at the college.

The thermograph is a machine that looks something like a television camera. The woman sits on a chair facing the thermograph, her arms raised and resting on a trapeze placed at eye level.

Tumors give off more heat than normal tissue, Dr. Milbrath explained, and the thermograph is able to make a picture of radiation given off anywhere in the body.

"Normal breasts give off the same amount of heat," he said. "If abnormal heat is coming off one of the breasts, it's not necessarily a cancer. But it is a signal light saying something may be wrong. It makes us look more closely at the mammogram.

WIDE LATITUDE

"Thermography gives us a wider latitude," he said. "We see the entire breast from the skin back to the rib cage, up into the arm and shoulder."

The mammogram is an X-ray of the breast obtained by the highly refined technique of xeromammography. A balloon at the end of the X-ray device compresses the breast, making it the same thickness throughout, so it's possible to see back to the chest wall.

The Breast Screening Project here is one of 28 throughout the country that are paid for by the National Cancer Institute (a government agency) and the American Cancer Society.

The Milwaukee project was begun last July on a $5,000 grant for a year and has been given an additional $5,000 to extend the screening to two years.

There is about a year's wait for the free examination here, but women are encouraged to call and have their names placed on the waiting list. Women 35 and older are eligible.

Statistics show that more women are killed by breast cancer each year than by automobile accidents. One out of every 15 American women develops cancer of the breast.

"We've made progress in the treatment of other forms of cancer, but the mortality rate for breast cancer hasn't changed in 40 years," the doctor said. "We've got to do something."

AN EFFORT

The Breast Screening Projects are an effort to do something. Each week data from the projects are sent to the University Science Center in Philadelphia for evaluation.

It's possible, Dr. Milbrath said, that the data results will show the way to an effective, inexpensive way to reach more women at less cost. He suggested that it might be a screening by mobile units of the type now used for the detection of lung diseases.

"Lung cancer is something we can prevent—stop smoking—but usually not cure," he said.

"In contrast, we don't know what causes breast cancer. We can't prevent it. But we can cure it if it's caught early enough.

"Is it worth it to the community to fund early detection of cancer?" he asked. "I think it's worth it and it can be done for a minimum of cost. We're looking for the way."

X-RAY PROCESS CUTS RADIATION DOSAGE

NEW YORK (UPI).—Noted radiologist Dr. Philip Strax has found a way to cut by 90 per cent the radiation needed to make a cancer-detecting X-ray picture of the female breast.

The pictures are mammograms. There is some concern in the scientific community that routine mammography over the years at current doses may cause harm from radiation.

A low-level mammogram delivers from two to three rads—the measurement of the strength of an X-ray. Dr. Strax said in an interview he can get better pictures with from one-fifth to one-third of a rad—using an image enhancer over the X-ray film.

Dr. Strax, the nation's top authority in mass screening techniques for breast cancer, said he has been testing the new method for the last several months.

"By using an image enhancer over the X-ray film we can make one rad do the work of ten—and we get a surprisingly much better picture," he said.

Mammograms are being used in a nationwide breast cancer screening program involving up to 270,000 women being examined at 27 detection centers.

The program, conducted by the National Cancer Institute and the American Cancer Society, was prompted by results of a study started in 1963 and directed by Dr. Strax.

That showed physical examination and mammography in breast cancer screening increased the rate of long-term survival after the detection of cancer in women over the age of 50.

Dr. Strax is a member of the American Cancer Society's Breast Cancer Task Force and the National Cancer Institute's Committee on the Diagnosis of Breast Cancer.

He said there is an urgency to reducing the rads in screening programs that include mammograms in private as well as public programs.

He said there is also a need to regularly inspect the equipment nationwide in clinics, hospitals and doctor's offices to curb possible harm from poorly maintained machines leaking radiation.

"In these programs the only thing to worry about is possible harm from radiation," he said. "We can't pooh-pooh that possibility."

Dr. John C. Bailar III, editor of the Journal of the National Cancer Institute and a critic of mammography at the two to three and higher rad level, said Strax' technique "will have a significant lower risk from mammography."

He said in one survey of mammography being done by private doctors dosages of up to 70 rads have been detected.

[From the Forum International]

SAFER BREAST CANCER DETECTION

A new breast X-ray technique which gives eight to ten times less radiation than other machines could save the lives of more than 26,000 women this year. The new technique—the Xonics Electron Radiography system—has been called "a major medical breakthrough" by X-ray expert Dr. George Jacobson of the University of Southern California School of Medicine.

"The new system gives the lowest X-ray exposures available anywhere in the world. There's no other system that can produce mammograms of such high quality at such low dosage," says Dr. Jacobson.

Another expert, Dr. John Martin, chairman of radiology at St. Joseph Hospital in Houston, Texas, explains that breast cancer will strike one of every thirteen women, killing 33,000 this year. But Martin claims that at least 20 percent of them could have been saved if they had come in for early mammography examinations.

Mammography is the only true early detection method for breast cancer, since this technique is able to spot as much as 45 percent of breast cancers that cannot be felt by the hand and therefore are not detected through manual breast examinations.

Dr. Martin explains, "Unfortunately, many women are alarmed at possible dangers from X-ray dosages, so they don't take the examination. But with this new system the dosage is so low that the danger is insignificant."

According to the senior research scientist for Xonics, the average radiation with present X-ray equipment is 400 to 1,000 milliards. The new Xonics system produces excellent mammograms at only 50 to 100 milliards of radiation. The Xonics Electron Radiography system will be in hospitals throughout the U.S. early this year.

According to Dr. Philip Strax, medical director of New York's Buttman Institute, "It's at the early stages that breast cancer is most curable. If there's a mass screening for early breast cancer detection, up to 80 percent of the women who will die from the disease will be saved."

EXPERT DEFENDS SAFETY OF MAMMOGRAMS

By Joann Rodgers

Robert L. Egan, professor of radiology at Emory University School of Medicine in Atlanta, was the first to develop mammography as a practical, effective method of detecting early breast cancer.

That was in the 1950's while on the staff of the M. D. Anderson Tumor Institute in Houston. After 25 years of experience with mammograms, he recently agreed to answer some of the persistent and confusing questions and criticisms many women—and their doctors—have about the technique.

Q. Are mammographs dangerous?

A. Claims that mammography causes more cancer than it detects are based on the most fragmentary, and least pertinent, bits of information about the technique. And women's lives are seriously jeopardized by such claims.

Q. But some of those claims are made by physicians and cancer experts. Are they completely off base?

A. Physicians and women should view with great reservation the predictions of a few critics who are neither bona fide radiologists, oncologists (cancer specialists) or epidemiologists about the hazards. Much of the criticism is political, sensational and taken out of all proportion.

Q. Then there is some validity to the claims?

A. Good radiologists have always known that radiation is hazardous. Those of us who daily deal with X-rays know also how important it is to keep dosage at a minimum and to weigh the risk of an X-ray against the possible benefit. We have evidence, for example, that some breast X-ray machines deliver 20 to 40 rads (1 "rad" is a standard unit of absorbed radiation) per mammogram, which is uncalled for. Our radiology service delivers about 1 rad per mammogram. The point is to correct the abuses of mammography, not frighten all women away from the tests.

Q. How can women make certain a radiologist and his equipment are offering the safest possible mammography?

A. Quality control isn't easy. But there are a few guidelines that should help. First, it's probably best to have your mammogram done at a cancer center, or by radiologists whose primary affiliations are with cancer centers. Check out the radiologist's certification and training. Ask questions about his equipment, such as its age, where it was manufactured and how many rads it delivers.

Q. What about atlernative early diagnostic techniques, such as ultrasound, and Xeroradiography, which deliver no—or very little—radiation?

A. These are of interest and some value. But they are, in my opinion, much inferior in terms of detail and diagnostic value. I believe mammography is the only early diagnostic technique we now have that is accurate and safe when done properly. The vast majority of breast cancers are in women over 50—86 per cent at Emory, for example. But our statistics also show that in women 30 to 65, there are 11.5 cancers per 1,000 women.

Ninety per cent of all those we found with mammograms were very early, non-spreading cancers with no—or only one—lymph node involved. And a third of these early cancers, the most curable ones, were in women under 50 on whom we could do simple mastectomies. That is, just take off the breast and not perform more radical disfiguring surgery. These are the women who have the longest lives to lose if they aren't diagnosed early and the longest to survive and enjoy if they are.

NOTE.—The American Cancer Society-National Cancer Institute mammography guidelines recommend that all women over 50 have routine mammography. In women under 50, they recommend mammography for anyone with unusual breast symptoms or anyone at higher than normal risk for breast cancer. And they agree that a "baseline" mammogram in any woman—with or without risk or symtoms—for later comparison is a valid option in good medical care.)

[From the National Aeronautics and Space Administration]

Richard McCormack, Headquarters, Washington, D.C., (Phone: 202/755-8487).
Mark Hess, Kennedy Space Center, Fla. (Phone: 305/867-2468).
Release No: 77-102.

SPACE TECHNOLOGY MAY LEAD TO EARLY DETECTION OF BREAST CANCER

Every year thousands of women are subjected to screening procedures for breast cancer which use potentially harmful X-rays. Many of these women go through the physical and emotional anguish of radical surgery in the treatment of this disease.

Repeated X-rays have often been considered necessary because developing stages of breast cancer are sometimes undetectable by doctors who examine the earliest breast X-rays, making early diagnosis more difficult and sometimes allowing cancerous tissues to multiply until massive surgery is the only solution.

For two years engineers in the Data Analysis Facility at NASA's John F. Kennedy Space Center, Fla., have been working on the problem. The experimental process involves techniques similar to those originally developed to analyze imagery transmitted from Landsat satellites. By applying these space techniques to the medical field, engineers have developed a method which may enable doctors to detect early stages of breast cancer and to determine the likelihood that a woman will ever develop breast cancer.

This experimental technique for early cancer detection is a product of X-ray enhancement—the ability of computers to enhance or make more visible information from X-rays not ordinarily detectable by the human eye.

Trained radiologists who examine X-rays work with a built-in handicap—the human eye. The eye has difficulty in detecting small density changes or changes in the gray shades of the intensity spectrum's upper density region. Most X-ray data is within this upper density region.

The human eye—even the most highly trained one—can detect about 32 different shades of gray at best. For radiologists this means that much of the information contained on an X-ray is invisible to them.

The need is for a method of putting these undetectable shades of gray in a better perspective—enhancing them so they are easily visible.

This is where the Data Analysis Facility steps in with its General Electric "Image 100" multi-spectral image analyzer. It is a computer-controlled system which extracts and classifies information about an image much better than can be done by human means.

Shades that were previously invisible to a doctor's eyes are now analyzed in much more detail. This makes significant information visible much earlier, improving prospects for an earlier diagnosis.

The special optical tool that begins this process is called a microdensitometer. Far superior to the human eye, it can detect 256 shades of gray with great accuracy.

The microdensitometer scans a photographic image—such as an X-ray and then puts the information into computer language. The information is then fed into the Image 100 with instructions to enhance the low visibility gray shades. After classifying the gray shades which make up an image, the computer displays them in a way that is more meaningful to the radiologist.

Robert L. Butterfield, an electronics engineer at the Data Analysis Facility, has been working with the Image 100 and a Titusville, Fla., radiologist, Dr. William L. Walls, for two years on a process in which mammograms (breast X-rays) can be automatically analyzed to detect early stages of breast cancer before radical surgery is needed.

The current goal is to try to develop a computerized method of separating those women who are in a low risk group (least possibility of developing breast cancer) from those in a high risk group (high possibility of developing breast cancer). If this method becomes feasible, it should reduce the need for repetitive screening-type mammograms.

The new X-ray analyzing system, if the development effort is successful, may allow separation of women into low, medium and high risk groups, allowing radiologists to concentrate on the mammograms from the high risk group.

Medical persons and engineers hope that some day this method may lead to techniques that would allow detection of very early breast cancer. Depending on the rate of change in X-ray gray shades, the yardstick doctors use to diagnose various stages of breast cancer, the computer may yield information enabling the radiologist to determine if very early indications of breast cancer are present.

[From the Federal Register, Vol. 41, No. 113—Thursday, June 10, 1976]

[Docket No. 76N–0210]

RECOMMENDATIONS CONCERNING MAMMOGRAPHY

INVITATION TO SUBMIT DATA, INFORMATION, AND VIEWS

The Food and Drug Administration (FDA) is inviting the submission of data, information, and views on voluntary radiation safety recommendations to minimize unnecessary radiation exposure associated with mammographic examinations. Comments and data should be submitted by September 8, 1976 to: Office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

The Food and Drug Administration, through the Bureau of Radiological Health and under authority of the Radiation Control for Health and Safety Act of

1968 (Pub. L. 90-602, 42 U.S.C. 263b et seq.), conducts and supports research, training, and operational activities to minimize unnecessary exposure of the public to electronic product radiation. In carrying out the purposes of the act, the Commissioner of Food and Drugs is authorized to make such recommendations relating to the control of electronic product radiation as he considers appropriate (42 U.S.C. 263d). In this capacity, the Commissioner is considering the development of recommendations to health practitioners and public health officials concerning minimization of unnecessary radiation exposure in the conduct of mammographic examinations.

These recommendations would be among several that will be proposed by the Commissioner concerning the hazards and control of electronic product radiation or radiation from other sources. Some of these recommendations may be established in areas or activities inappropriate for mandatory control and thus would be voluntary. They will be developed in cooperation with national scientific and technical authorities and representatives of professional, public, and private groups that have an interest and knowledge in the field. The recommendations would therefore represent a consensus of export opinion upon which individual practitioners and allied health personnel can rely. These recommendations, which will provide guidance on techniques for reducing unnecessary exposure to electronic products or other sources of radiation, would be implemented through educational programs and cooperative activities with professional organizations and State health agencies. This notice is being issued pursuant to FDA policy of early public participation in the development of radiation protection recommendations by the agency.

Mammography is currently a widely used and accepted diagnostic examination for breast cancer detection. Practioners employ several mammographic techniques. The range of radiation exposures associated with proper use of these techniques has been reported to be from less than 1 to over 10 roentgens per view at the surface of the breast, with 2 or 3 views of each breast comprising a typical examination. This variability in exposure is due to a variety of factors, some of which relate to the equipment and technique used and others which relate to the specific diagnostic information of interest. A large segment of the adult female population is likely to undergo a number of mammographic examinations and thus may be subject to a significant exposure to ionizing radiation.

The medical community and public health officials are currently developing methods to minimize the radiation exposure associated with mammography, while still retaining the desired diagnostic information. The Food and Drug Administration has encouraged the implementation of facility-based quality assurance programs in all diagnostic x-ray facilities, including mammography facilities. The goal of such programs is to assure that the facility will produce consistently high quality radiographs at minimum cost and minimum patient exposure.

An advanced notice of the intent to develop quality assurance recommendations was published in the FEDERAL REGISTER of May 7, 1976 (41 FR 18863). Other FDA activities, such as the publication of quality assurance procedure manuals, the development of equipment catalogs, etc., will provide guidance to diagnostic x-ray facilities as an aid to implementation of individual quality assurance programs. These facility-based programs are expected to minimize unnecessary radiation exposure during all diagnostic x-ray examinations, including mammographic examinations.

Because of the extra potential for high exposure in mammographic examinations, the Commissioner proposes to pursue two additional concurrent projects to minimize unnecessary radiation exposure in this area:

1. The Bureau of Radiological Health has begun pilot tests of a state-based quality assurance program in mammography. The state-based programs is designed to identify mammography facilities requiring special attention. In conjunction with one State and one local health department, cooperating clinical facilities are mailed thermoluminescent dosimeters to be exposed at those mammographic technique factors that are used in the craniocaudal view of the "average" breast. In addition to the dosimetry, data are also collected on the type of image receptor and processing, and on the number and age of women being examined. Facilities at which the exposure appears to be high for the image receptor used are visited by trained persons from the appropriate radiation control agency; these persons try to make recommendations to improve

one or more aspects of the technique. The goal of the improved technique is to reduce exposure while retaining or improving diagnostic capability. The information obtained by these pilot studies will be used to make recommendations for state-based mammography quality assurance monitoring and followup procedures, which will be available to all radiation control agencies nationwide. The information is also expected to be of value in implementing the facility-based diagnostic x-ray quality assurance programs.

2. The Bureau of Radiological Health proposes to compile a report that will contain information on technique-equipment combinations presently being used or promoted for use. Currently, a variety of x-ray tubes, technique factors, and image receptors are employed in mammographic examinations. No consensus exists among investigators in the field on the optimal equipment or technique. It appears that the choice depends upon the experience and preference of the practitioner and upon what features he deems most important to visualize. For example, xeroradiography is claimed to be superior in visualizing ductal patterns, whereas diffuse masses may be more easily detected using film as the image receptor. This report would reference data on factors such as the following: x-ray tube target material, type and thickness of x-ray filter, peak kilovoltage, source-to-skin distance, image receptor, imaging qualities, and expected range of exposure to the patient. Such a report could then serve as a guide to the selection of the technique-equipment combination appropriate for minimizing patient dose while obtaining the desired informaton. The data used in compiling this report would then be used in conjunction with opinions from the medical community in developing radiation safety recommendations for equipment used in mammography.

Interested persons are invited to participate in developing the proposed recommendations by submitting written data, information, and views on the subject. Comments are particularly desired on the two items described above, namely, the state-based mammography quality assurance program and the mammography technique information report. All such submissions should be identified with the docket number in the heading of this notice and be filed with the Hearing Clerk, Food and Drug Administration. Comments received on or before September 7, 1976 will be considered by the Commissioner in formulating the recommendations. All recommendations and technical reports that result from this study will be published and made available to all interested parties by means of a notice of availability published in the FEDERAL REGISTER.

Persons or organizations who wish to receive copies of draft recommendations, reports, and any related documents distributed for review during development of the mammography technique information report should write to the Food and Drug Administration, Bureau of Radiological Health, (HFX–440), 5600 Fishers Lane, Rockville, MD 20852.

Dated: June 4, 1976.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.76–16781 Filed 6–9–76 ;8 :45 am]

Senator STEVENSON. The next witness is Dr. Lauriston Taylor, the honorary president of the National Council on Radiation Protection and Measurements.

STATEMENT OF DR. LAURISTON S. TAYLOR, HONORARY PRESIDENT, NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS; ACCOMPANIED BY COMDR. JAMES A. SPAHN, JR.

Dr. TAYLOR. Mr. Chairman, I have brought to the table with me Commander Spahn, one of the staff members of the National Council on Radiation Protection.

I would like to open by saying that it is a privilege to be invited to provide testimony before your committee on the broad subject of radiation health and safety, thereby bringing to your attention some of the viewpoints of a nongovernmental organization dealing with the operations of portions of the Federal Government.

My name is Lauriston S. Taylor and I am the recent past president of the National Council on Radiation Protection and Measurements—NCPR—a position held since 1964.

Following are the elements of my background of experience pertinent to the questions under discussion during these hearings: I have been a member, chairman, or president of the NCRP and its forerunners since their establishmnet in 1929, and I have been present at every meeting held during that period.

I was a founding member of the International Commission on Radiation Protection in 1928 since which time I have missed only one meeting.

In 1927 I was asked to come to the National Bureau of Standards for the specific purpose of developing a program on radiation measurements and radiation protection. In due course, I became chief of the Bureau's Atomic and Radiation Physics Division and Associate Director until I decided to retire in 1964 to be able to work more freely on radiation related matters, at the National Academy of Sciences and the NCRP. In my oral testimony I shall touch on only two major points, but I shall be happy to answer any questions arising from my extended written testimony.

For orientation, I should first point out that the National Council on Radiation Protection was constituted in its present form in 1964 by an act of Congress—Public Law 88-376. The Council consists of 75 members elected for 6-year terms with reelection possible. In addition, there are some 300 other scientists—physicians, engineers, and others—who work with various of our 60 committees. Elected members and members of scientific committees are chosen primarily (1) for their individual competence and expertise in the particular area of concern, (2) to provide an overall mix of competence including all others working with the Council.

In interaction with the radiation programs in the Federal Government at the present time, two major problem areas may be identified. The first of these is what may be described as a general misuse of the principles of maintaining radiation exposure levels "as low as practicable". It is frequently referred to as ALAP.

The principle of maintaining radiation exposure "as low as practicable" was introduced by the NCRP in 1948 at which time it was regarded, and still is, as a sound principle of effective industrial management in any field involving health and safety. The principle was subsequently adopted by the International Commission on Radiological Protection with the name changed to "as low as readily achievable" and explained in a few thousand more words. There is no difference, either in fact or intent, between the NCRP and the ICRP in this regard.

It was then, and still remains, the intention of those two bodies to provide a system of basic permissible dose standards for radiation workers and for the general population. At the time that these levels were first produced, the caution of maintaining radiation exposure generally as low as practicable was put forward. The purpose was to emphasize that while the basic standards were regarded as adequate and justifiable, it was usually possible, and usually standard industrial practice, to maintain working levels in individual installations as well below those which were regarded as basic and acceptable. This was, in part, to avoid the possibility of administrative overruns in exposure, but more importantly was regarded as good safety practice. An essential ingredient of ALAP is that it places the responsibility for good radiation protection practice on the user.

Basic protection standards for ionizing radiation were first set by the NCRP and then the ICRP in 1934. These were subsequently adjusted downward by the NCRP and then the ICRP in 1948 and 1950, respectively. Further adjustments were made in 1957 by the NCRP and subsequently in 1959 by the ICRP.

In 1969, after many years of continuous study and review of these basic permissible dose standards, the NCRP reaffirmed the basic structure of its 1957 recommendation. Also after substantial study, the ICRP in 1977 is reaffirming its basic concepts for permissible dose standards. Those have not yet been published.

As mentioned above, the principles of maintaining radiation levels "as low as practicable" was designed to encourage work at reduced levels but at the same time to provide a degree of flexibility and the use of common sense and judgment which apparently is not possible within any rigid regulatory structure. It was designed to allow adjustments in individual working conditions to cover a wide variety of situations, the total of which are covered by the basic permissible dose standards.

The trouble is that the normal regulatory process, whatever its advantages may be, eliminates flexibility and judgment, and by the very process of regulation restricts or even eliminates the use of new experience and commonsense. As soon as an agency issues radiation control numbers under the cover of ALAP, the new numbers for all practicable purposes become new standards no matter how you label them. This is exactly what has been happening with the radiation protection guides that have been proposed within the last couple of years by the Nuclear Regulatory Commission or the Environmental Protection Agency.

In 1972 the NCRP was invited to testify at the hearings on 10 CFR 50 being held by the AEC dealing essentially with the ALAP principle. Following is the essential point covered in the above testimony:

"The implications arising from the attempted use of the 'least practicable' concept in regulations are of concern to the NCRP. It is generally accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed, this is one of the prime virtues of laws or regulations. The 'low as practicable' concept, however, has merit precisely because it allows deviation from the radiation protection standards which are, indeed, designed to be applicable to all. The attempt to specify by regulation what is 'least practicable' appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential, and yet removes from those subject to the regulation the responsibility for ascertaining what need be done to meet the 'least practicable' criteria."

The NCRP has no particular reason to complain about the use of low levels of radiation exposure such as proposed by the EPA and the NRC for light water-cooled reactors. It does, however, complain about the issuance of these new control numbers under the guise of the ALAP principle. Regardless of how they are described, and perhaps restricted to certain situations, these numbers nevertheless become identified as exposure "standards". The result of this is a complicated and almost meaningless matrix of standards, many of which are impractical or impossible of direct maintenance. Moreover, the use of such numbers has a strong tendency to lull the consciousness of the radiation user into failing to meet the need to be continuously alert and responsible in radiation protection matters.

Once such numbers have been generated and become "official" it is politically impossible to raise them at some later time should circumstances indicate the need. Once such numbers have been cranked into the dogma of radiation protection standards, they become monolithic. I can well visualize the time when, for good reasons and with reasonable safety, it may become necessary to adjust some of these numbers upward.

It should be reemphasized that however low the present control numbers may be, and whatever they may be called, no reason has been found to change the basic radiation protection standards for radiation workers or the population.

To deal with the misuse of the principle "as low as practicable" we recommend:

(*a*) Adherence to the basic maximum permissible dose levels or dose limits established by the NCRP or the ICRP and contained in their most recent publications.

(*b*) As an alternative to that, have some Government agency come right out, frankly and honestly, and change the standards on a justifiable biomedical and political basis.

(*c*) Use of the conventional, industrial procedure of working out radiation levels that are lower than the basic permissible limits but allowing some judgment in the degree to which lower working levels may be employed.

(*d*) Retention of the intended flexibility of the principle of maintaining radiation exposure levels as low as practicable.

(*e*) Stop hiding oppressive radiation control numbers under the subterfuge of ALAP or other new names or new definitions that may crop up.

(*f*) And finally, recognize a structure of basic radiation protection standards for workers and the population, noting that such a structure now exists and is in use the world over.

The second broad area of concern has been the transfer of the responsibilities of the Federal Radiation Council, as established in 1959, to a single Federal agency which must live and operate in parallel with many other Federal agencies having legitimate concerns with health and safety in the field of ionizing radiation.

In the late 1950's, it was recognized, as a result of hearings by the Joint Committee on Atomic Energy, that the Federal Government had no mechanism for establishing radiation protection standards and had always been in the position of having to accept those developed by the NCRP (then the National Committee on Radiation Protection). The problem was studied in depth by Dr. Robert Cutler in the Bureau of the Budget in 1959. The concept of establishing this responsibility within any single Federal agency was examined and completely rejected. In addition to discussions with various agencies and outside groups, the matter was considered by the NCRP, and I was personally very deeply involved in many of the discussions. After the FRC was established, I became a member of its working group and from time to time a member of the FRC itself, acting on behalf of the Secretary of Commerce.

The major findings of the Cutler study at that time included:

(*a*) No one agency could provide the breadth of coverage needed for the development of radiation protection standards.

(*b*) No one agency could be assured, in the field of radiation protection, of adequate cooperation by all other concerned agencies.

(*c*) Interagency committees in the normal sense were traditionally ineffective and frequently served only for window dressing.

(*d*) Bureaucratic "necessities" stimulate a kind of rivalry that is costly and inefficient.

The original objectives assigned to the Federal Radiation Council were to adopt or develop protection standards needed by the Federal Government to carry out its individual Federal responsibilities. This was needed because of the discovery that up until then the Federal Government had been in a position of having to essentially accept the standards recommended by a body (the NCRP) over which it had no control. This was clearly recognized by the Government as well as by the NCRP as an untenable situation.

A critically important feature of the FRC was its mode of operation. The FRC itself was composed of department heads (Cabinet officers), but each in turn assigned one of his top radiation experts to a "working group" that met weekly. It was their responsibility to consider the technical details and endeavor to reach agreement among the several agencies represented. This was then modified or approved by the most senior officers in the Government with a stamp of authority that could not be achieved were the FRC in any single agency.

It its first activity after its formation in 1959, the Council made an intensive study of permissible dose standards. This study drew in representation from Government agencies, Government laboratories, and many parts of the private sector—individuals with established reputations for knowledge and experience bearing on the subject. Following this intensive study, the FRC in its Report No. 1 adopted as basic standards for Government use, those that had been recommended by the NCRP and were already in use throughout the country.

However, by this action on the part of an established government body, what had always been "recommendations by the NCRP" thenceforward became the standards of the U.S. Government for U.S. Government use. And I would add that the NCRP does not regard itself as a "standards setting" body.

It was an excellent example of the system that can evolve through close cooperation between Government and private bodies.

When the Environmental Protection Agency (EPA) was established by Mr. Nixon under Reorganization Plan No. 3 of 1970, the functions of the FRC were transferred to the new organization without any change in the language from the original Executive Order EO-10881 or the subsequent amendment to the Atomic Energy Act of 1954.

As the situation appears today, it would seem that the EPA has grossly overextended its interpretation of the FRC responsibilities to positions that are far beyond the original objectives which applied to the Federal Goverment only. I believe that the proper interpretation of the original intent in the establishment of the FRC is clearly shown by the eight FRC reports which were issued prior to the establishment of the EPA.

Among improper areas of special concern are those in the general area of medical practice, patient dose limitation, shielding in medical installations, occupational exposures, and so on. In this connection, EPA has openly stated their intention to extend their areas of concern to nongovernmental medical practice by their own interpretation that any services reimbursed by medicare automatically fall within the FRC scope of "Government needs." It is difficult also to see how any such interpretation can fall within the structure of "environmental protection." Their attitude toward using medicare as a lever for Government control shows a clear recognition of the fact that some kind of subterfuge was needed to support their extension of the stated FRC objectives. The EPA inclusion of general medical radiological procedures, either under FRC or environmental protection philosophy, overtaxes the imagination.

Such interpretation would place any regulatory, advisory, or control responsibilities in an organization and atmosphere that is professionally and intellectually malsuited to the problem. If radiological practice, because it touches upon such a large fraction of the population can be described as environmental—then so can practically every other profession or business.

I do not want to leave the impression that the EPA is not carrying out much of its mission. EPA has a large, proper, and important role in the management of ionizing radiation in the environment. This would include such areas as radioactive contamination from uranium mill tailings or the manufacture of radioactive components, fallout from an accident or weapons testing, management of a radiation surveillance network, radioactive byproducts from industrial operations such as mining of phosphates, et cetera, et cetera, et cetera. The intellectual and professional atmosphere of EPA is well adapted to meet such responsibilities.

EPA has a small dedicated staff that can manage the problems properly categorized as "environmental" by any argument and they should be encouraged to do the job.

Senator STEVENSON. Thank you, Dr. Taylor.

You heard Ms. Kushner's statement, I believe. Should we be unconcerned about the qualifications of the technicians who administer the X-ray examinations? Is that a concern of yours and the NCRP?

Dr. TAYLOR. We have not addressed ourselves to this particular question. This has involved consideration by outside organizations. It has never been brought to us, and we have not become involved in it.

I would say nobody can be indifferent to the qualifications of the radiological technicians.

Senator STEVENSON. Is it a problem that requires some action from the Government at some level?

Dr. TAYLOR. Probably.

But again I think this is a case of where we have to look at the problems that are introduced by treating the problem by regulatory procedures as against educational procedures. And I don't feel that I am qualified to discuss that question very much.

Senator STEVENSON. Well, let me ask also about the equipment. It is one thing to agree on an acceptable standard, but in addition to the qualifications of the technicians should the equipment also be inspected periodically to insure that its integrity is maintained, that it complies with applicable standards?

Dr. TAYLOR. Yes. I think the equipment should be inspected periodically, yes.

Senator STEVENSON. Do you believe it is inspected sufficiently now, throughout the country?

Dr. TAYLOR. It is probably quite spotty. Some States have good equipment inspection programs. And others have relatively nonexistent programs, very meager programs, if any at all. This again is a question which I would think normally would be best covered by local agencies rather than by a Federal type of action: State, city, so on.

Senator STEVENSON. Do you think we need some Federal effort to help establish uniform standards, or are the States capable of doing that?

Dr. Taylor. That is being done. I think the program of the Bureau of Radiological Health is a very effective measure in this direction. Through their contacts throughout the country, which I referred to in my extended testimony, they are able to accomplish a great deal in the way of promulgating their general standards and recommendations.

Commander Spahn has just called my attention to a program that had slipped my mind; this is the Joint Committee of Accreditation of Hospitals operated out of Chicago. They have extensive programs of this sort. We have cooperated with them in helping to provide the necessary background material for their requirements for hospital equipment operations. We have not become involved in the program ourselves.

Senator STEVENSON. On the question of permissible dose standards, you say they have been reduced over time. Not because of any data indicating radiation to be more hazardous but because the technology has improved.

Could you elaborate on that? If I understand what you are saying it is that the technology is determining what dose standards are permissible, what is considered safe.

Do you really mean that?

Dr. TAYLOR. Well, to some extent that is correct. Let me go back to the beginning.

In 1934, the standard that was set by the NCRP amounted to one-tenth of a roentgen per day. That is, depending upon how you count it, about 30 roentgens per year.

At the same time the ICRP set their standard at twice that, in other words, 60 roentgens per year.

In 1948, this was lowered to the equivalent of 15 roentgens per year by the NCRP and then the ICRP. This was done at the time partly because it was beginning to be recognized that there might be some unexpected effects. And it was done very much because the industry and technology had reached a point where this could be done; this reduction could be made without depriving the public of needed uses of radiation.

There was no biological information and there is none today to indicate that for radiation workers the exposure levels need to be less than 30 roentgens per years. There is no indication of injury to radiation workers at those levels.

In 1956, the middle 1950's, the levels were again lowered—then very much because of "new" genetic information—and again because of the practicability of accomplishing this within our available technology.

By 1960, or therabouts, it was demonstrated that the genetic reasons for having lowered the levels in 1956 were incorrect, and we could have left them alone. However, by that time they had been pushed down. They were accepted. And so the levels were left as they are.

Throughout all of this, from 1934 to date, with radiation workers who may have been exposed within those levels, there is no single identifiable case of injury or effect to those people.

Does that help you?

Senator STEVENSON. Not much.

You seem to be suggesting that there ought to be proof of injury before the standard is established or reduced.

Dr. TAYLOR. Well, you can look at that two ways. Certainly, at the time that these standards were being set in the thirties, forties, and fifties, proof of injury was indeed an indication of whether you should set standards. The normal practice in toxicology and in other areas was to find an effect, try to find a level below which you could find no effect and then set your permissible level at a tenth of that.

Senator STEVENSON. Well, I think the basic proposition is highly questionable. But the second part of what you said I just don't understand. There certainly has been evidence of injury from exposure to radiation, through X-rays.

Dr. TAYLOR. Of course.

Senator STEVENSON. And hasn't that brought about a reduction in the exposure standards?

Dr. TAYLOR. The levels at which injuries have been observed, and at which effects have been observed are very high doses, very high doses compared to any that we are talking about in industry or for the general public or in most diagnostic procedures.

Senator STEVENSON. Let me be a little more specific.

Have the dosages of radiation that were permitted in the late thirties, let's say, after 1934, been connected to malignancies of the thyroid?

Dr. TAYLOR. The chronic doses as recommended in 1934?

Senator STEVENSON. Yes.

Dr. TAYLOR. No. They have not been linked to thyroid injury. Bear in mind another point here, when we are talking about doses for radiation workers, we are talking about very small doses distributed uniformly, over a long period of time. And where we talk about 30 roentgens——

Senator STEVENSON. Let's talk about patients, people who have been given X-ray treatment. They were given treatment in accordance with permissible standards in the late thirties, were they not?

Dr. TAYLOR. No, no. Permissible standards have nothing to do with therapy. Permissible standards are for the public who might be exposed to very low levels. When you are talking about therapy you are treating a disease and you are giving very large doses of radiation. And there can be very gross effects.

Senator STEVENSON. All right. Let me ask you about nonionizing radiation. You indicate that the NRCP undertakes continuous systematic study and review of radiation protection standards.

Does this include investigation of suspected nonthermal effects of both high and low level nonionizing radiation?

Dr. TAYLOR. That statement should apply primarily to ionizing radiation. We have two committees dealing with nonionizing radiation but neither of these committees have reported as yet. Commander Spahn, can tell us about that.

Commander SPAHN. We have two committees that are concerned, one with measurement techniques for the microwave fields, and the other one with the biological effects of microwaves. The Measurement Committee is in the final drafting stages of its report. And we would hope very soon to have some results from that report.

The Biological Effects Committee has just held its first meeting. So, we can anticipate some delay before we see any results from that report.

Dr. TAYLOR. In the letter that we received, a question was asked, about the relationship between the standards for microwave radiation in the United States as compared with eastern European countries. And I am sure this meant specifically the Soviet Union because they are the only country that I know of that has such standards. Their standards have been set, or they have talked about standards, at levels substantially less than ours. I am not sure the exact factor of 10 or 100. Sometimes I see 1,000.

However, we are informed by the chairman of our Biological Effects Committee, who has just returned from the Soviet Union within the past few days that there they are now reconsidering their evaluation of the problem and are talking themselves about adopting the same level that we are using now in the United States.

Senator STEVENSON. Would you tell us who that was, who reported that?

Dr. TAYLOR. This was Dr. Guy, chairman of our Committee on Biological Effects of Microwave Radiation.

Senator STEVENSON. I am told that their standards now for exposure to microwaves is 1/1000th of ours.

Dr. TAYLOR. I believe that is correct. And they are now talking about increasing that to the same level that we are using, and that is being used in the rest of the world.[1]

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[1] The Committee has been informed by various American scientists that the Soviets are merely reassessing their exposure standards at the present time.

Senator STEVENSON. You said, Dr. Taylor, in your testimony, with respect to ionizing radiation standards you could visualize a time when for good reasons, with reasonable safety, it may become necessary to adjust some of these standards upwards. What are those circumstances that you visualize?

Dr. TAYLOR. Well, this is getting out into the blue yonder. But on the other hand, we, in this country, and the rest of the world are facing power shortages. And I think there is a reasonably good likelihood that at least on an interim basis we may be compelled to go more into nuclear power than we are talking about today. Nuclear power is not my particular concern.

On the other hand, we have as an example for light water reactors, what I would call, "operating numbers" for exposures from the complete fuel cycle.

Those are extremely low. And if they had to be doubled or tripled or multiplied by 5 or 10 for sufficiently good reasons, I don't think that the public would be endangered beyond some acceptable point. This is just my thinking about the problem. I am not involved in it at all.

Senator STEVENSON. Senator Schmitt.

Senator SCHMITT. Thank you, Mr. Chairman. Dr. Taylor, has your council looked into the insidious radiation sources, such as television sets and other things to which people are exposed without realizing it?

Dr. TAYLOR. I can mention two areas. We became concerned about the possibility of radiation from television back as far as about 1959, or 1960, at which time we issued a short recommendation setting a permissible level—I don't remember the number at the moment—it doesn't matter. Because of the accent on this problem in the late 1960's, we did this a second time more thoroughly and on a crash basis. We came up with a report and recommendations, and those recommendations and numbers are the ones that are now being used by the Federal Government. That is one area.

In another area, we have a committee that is looking generally at the problem of radiation that may be involved in connection with consumer products. This, I would think, would cover——

Senator SCHMITT. Such as fire detection devices?

Dr. TAYLOR. Yes, fire detection, television, burning oil in your gas heaters in the house, oil heaters, burning coal in your furnaces, having medical X-ray examinations, some 30 items of this sort which impinge rather directly on the public demand.

Senator SCHMITT. Is the average person exposed to levels higher than the industrial standards which you mentioned earlier?

Dr. TAYLOR. No. No.

Senator SCHMITT. They are well within those standards?

Dr. TAYLOR. Yes; well within them.

Senator SCHMITT. What about the child who sits a meter from the television set for the better part of the first 6 or 7 years of his life?

Dr. TAYLOR. The levels are such as to be acceptable at a distance of a couple of inches from the set. So that if you are sitting a meter away, of course, you are obviously better off because of the inverse square law. Somehow it has come into public circulation, that a distance of 2 meters is safe for television equipment.

I would say that the main risk that a child would suffer from getting closer to the television set is injury to his eyes, just from the image itself, not from the ionizing radiation.

Senator SCHMITT. Being too close?

Dr. TAYLOR. Yes.

Senator SCHMITT. I remember when we were using X-rays at the university. We would use the rule of thumb that a meter was sufficient for the use of various fractometers. Do you agree that is a safe distance?

Dr. TAYLOR. No; I would not say any such number at all. I would say that if it is necessary to stay within 6 inches of the machine, put enough shielding in between it and you. Or you might have to get 100 yards away. There is no real answer to that question.

Senator SCHMITT. You have not looked at the research equipment of various kinds?

Dr. TAYLOR. Yes; over the years we have looked at this to a certain extent. But even more, when I was with the National Bureau of Standards, we had a very extensive program of studying X-ray and other types of equipment that might give off ionizing radiation. For a number of years, we inspected all of the equipment that was bought, for example, by the Veterans' Administration and the Army.

Senator SCHMITT. One problem with equipment that is in general use, whether it is in the medical or research areas, is that it is being used by people. And people get careless.

Do you see any way in which legislation can be drafted so that people are not careless?

Dr. TAYLOR. It is almost impossible to make something idiot-proof. If something is going to be used by inexperienced people, you have to specify that there is no conceivable way by which the equipment can be disturbed in a manner that will allow radiation to escape to a serious extent. You can accomplish any of these things, if you want to. Personally, I don't think it ought to be done by broad regulation.

BRH is doing this for many things. And I think, while I am not completely familiar with its whole program, on the whole, they are doing an excellent job. And some of this is done by the standards which they promulgate. But I don't think that they are getting into the business of regulating and enforcing regulations to any great extent and I don't think they should.

Senator SCHMITT. There are certain geologic environments that are producing significant background radiation. Has the council looked into these environments where reasonable amounts are still traced, but pretty high amounts of uranium are involved?

Dr. TAYLOR. Not as such. A good example are the phosphate deposits.

Senator SCHMITT. Almost any old shield environments, as we sometimes call them, with granites of various kinds, have relatively high levels of background radiation.

Dr. TAYLOR. We have been very much aware of this. And we published a report covering all such sources of radiation. About 1 year ago the NCRP published a report covering all sources of natural radiation, but we do not try to specify what is safe in a particular configuration, as for example, phosphate mines in Florida.

We have standards of what we think are acceptable for the general public and for radiation workers, working in the deposit areas, let's say. But we don't try to tell them how to do their work.

Senator SCHMITT. That has to do with the industrial side of it. I am thinking of the people that live in proximity to these areas.

Dr. TAYLOR. That again, as I am sure you realize, is a very difficult problem. And again, our role is to say what we think is acceptable from all sources for people. What is acceptable, as far as we are concerned in this particular connection, is not influenced by whether the radiation comes from a medical X-ray machine or from radioactivity in the soil or fallout from a weapon. If it is radiation we will have some recommendations as to acceptable levels.

Senator SCHMITT. Have you looked into the rate at which radiation will be released by the generally expanded use of coal and lignite for the production of electricity?

Dr. TAYLOR. Yes; I am not sure it covers that specific one. We have looked at coal, oil, and gas.

This committee report on consumer products which is due out almost any day now will cover that. I personally don't happen to remember the numbers associated with it.

Senator SCHMITT. Mr. Chairman, it might be advisable to try to get a copy of that and make it a part of this hearing record.

Dr. TAYLOR. Do you have copies of our other reports, some of which I have already mentioned?

Senator STEVENSON. Not all of them.

Dr. TAYLOR. We would be happy to send you a collection of those [1]

Senator STEVENSON. Thank you. We would like also to take the liberty of following up after this hearing with some more questions.

Thank you, sir.

Dr. TAYLOR. Thank you.

[The statement follows:]

STATEMENT OF DR. LAURISTON S. TAYLOR

Mr. Chairman, it is a privilege to be invited to provide testimony before your Committee on the broad subject of radiation health and safety, thereby bringing to your attention some of the viewpoints of a nongovernmental organization dealing with the operations of portions of the federal government.

My name is Lauriston S. Taylor and I am the recent past President of the National Council on Radiation Protection and Measurements (NCRP), a position I had held since 1964.

Unfortunately, the current President, Dr. Warren Sinclair, is meeting with the Board of Directors of the Council at its 45th meeting, being held in Chicago. Since it was not possible on such short notice to reschedule the meeting of the Board, Dr. Sinclair has asked that I address your Committee.

Since my only connection with the Council at the moment is honorary, my testimony cannot be considered as strictly official. On the other hand, I have been intimately associated with the Council and its predecessor organizations since their original formation in 1929, and therefore any views which I express may be considered as resulting from long association with the NCRP.

Following are the elements of my background of experience pertinent to the questions under discussion during these hearings: I have been a member, Chairman, and President of the NCRP and its forerunners since their establishment in 1929 and I have been present at every meeting held during that period.

I have been a member of the International Commission on Radiation Protection since its founding in 1928 during which time I have missed only one meeting.

In 1927 I was asked to come to the National Bureau of Standards for the specific purpose of developing a program on radiation measurements and radiation protection. In due course, I became Chief of the Bureau's Atomic and Radiation Physics Division until 1962 when I was made an Associate Director. I decided to retire in 1964 to be able to work more freely on other radiation related matters, at the National Academy of Science and the NCRP. Since my first radiation protection work took place in 1922, at the Bell Telephone Laboratories, my work in the field has covered a span of 55 years. A more detailed description of my activities is avaliable if you wish.

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[1] The reports are in the Committee files and are available from the NCRP.

THE NCRP

The NCRP was requested by your staff and subsequently in a letter of May 31, to deal with two broad areas of concern in the field of ionizing radiation. The first of these was to comment on the various ionizing radiation programs currently found in the government. Secondly, we were asked to provide information on the current organization and activities of the NCRP, particularly in relationship to other organizations inside and outside of the government. It is our plan to concentrate on the first question and to provide data and information for the record on the second question.

For orientation, I should first point out that the National Council on Radiation Protection was constituted in its present form in 1964 by an Act of Congress (Public Law 88-376). The Council consists of 75 members elected for six-year terms with reelection possible. In addition, there are some 300 other scientists—physicians, engineers, and others—who work with various of our 60 committees. Elected members and members of Scientific Committees are chosen (1) for their individual competence and expertise in the particular area of concern, (2) to provide an overall mix of competence including others working with the Council, and occasionally (3) to bring to the Council some of the expertise from the organization with which they are associated. These people, members and committee workers, are drawn from all over the country, predominantly from the private sector, but including a few from government or government laboratories, and all (except the President) serve without compensation except for travel expenses. The Council has a small secretariat consisting of a paid staff servicing the 60 Committees. On the staff are five part or full time professional individuals and seven secretarial or administrative persons.

In our experience with the radiation programs in the federal government at the present time, we identify what we regard as two major problem areas. The first of these is what we would describe as general misuse of the principles of maintaining radiation exposure levels "as low as practicable". It is frequently referred to as ALAP.

The principle of maintaining radiation exposure "as low as practicable" was introduced by the NCRP in 1948 at which time it was regarded as a sound principle of good and effective industrial management in any field involving health and safety. The principle was subsequently adopted by the International Commission on Radiological Protection in name to "as low as readily achievable" and explained in a few thousand more words. There is no difference either in fact or intent between the NCRP and the ICRP in this regard.

It was then, and still remains, the intention of those two bodies to provide a system of basic permissible dose standards for radiation workers and for the general population. At the time that these levels were first proposed, the caution of maintaining radiation exposure generally as low as practicable was put forward. The purpose was to emphasize that while the basic standards were regarded as adequate and justifiable, it was usually possible, and usually standard industrial practice, to maintain working levels in individual installations well below those which were regarded as basic. This was, in part, to avoid the possibility of administrative overruns in exposure, but more importantly was regarded as good safety practice. An overall essential ingredient of ALAP is that it places the responsibility for good radiation practice on the user.

Basic protection standards for ionizing radiation were first set by the NCRP and then the ICRP in 1934. These were subsequently adjusted downward by the NCRP and then the ICRP in 1948 and 1950, respectively. Further adjustments were made in 1957 by the NCRP and subsequently in 1959 by the ICRP.

In 1969, after many years of continuous study and review of these basic permissible dose standards, the NCRP reaffirmed the basic structure of its 1957 recommendation. Also after substantial study, the ICRP in 1977 is reaffirming its basic concepts for permissible dose standards.

It is important to point out that during all of the periods since 1934 the changes in permissible dose standards which have been introduced were not because of new data indicating radiation to be more hazardous than previously thought. The changes were introduced primarily because of the practicability of accomplishing lower radiation exposure levels in keeping with the practical needs of the scientific, medical, and engineering community.

It should be emphasized again that these actions by the NCRP and the ICRP resulted from continuous, systematic study and review. Their reports and recommendations do not result from studies on an ad hoc or "time-to-time" basis that is the usual practice of other private bodies making recommendations in the field.

TWO MAJOR PROBLEMS

A. Misuse of the ALAP Principle

As mentioned above, the principle of maintaining radiation at levels as low as practicable was designed to encourage work at reduced levels but at the same time to provide a degree of flexibility and the use of common sense and judgment which apparently is not possible within any rigid regulatory structure. It is designed to allow adjustments in working conditions to cover a wide variety of situations, all of which are covered by the basic permissible dose standards.

The trouble is that the normal regulatory process, whatever its advantages may be, eliminates flexibility and judgment, and by the very process of regulation restricts or even eliminates the use of new experience and common sense. As soon as an agency issues radiation control numbers under the cover of ALAP, the new numbers for all practical purposes become new standards no matter how you label them. This is exactly what has been happening with the radiation protection guides that have been proposed within the last couple of years by the Nuclear Regulatory Commission or the Environmental Protection Agency.

For a while, it seemed pretty evident that each of these two bodies was trying to outdo the other in seeing who could make their "guides" or whatever they might be called the lower and more restrictive. In fairness, it should be pointed out that this kind of rivalry seems to have quieted down in recent times. It must have become evident to the agencies involved that it was non-productive and that a more cooperative stance had to be accepted.

In 1972 the NCRP was invited to testify at the hearings being held by the AEC dealing essentially with the ALAP principle. At those hearings, we directed attention to the misuse of the principles at that time. It must be pointed out, however, that since then it is our judgment that the principles have been much more seriously undermined and misused.

Following, for the record, is a copy of a portion of the testimony that we presented at that time (The Development of Radiation Protection Standards, AEC Hearing on 10 CFR 50, January 12, 1972). The essential point covered in the above testimony follows:

"The implications arising from the attempted use of the 'least practicable' concept in regulations are of concern to the NCRP. It is generally accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed this is one of the prime virtues of laws or regulations. The 'low as practicable' concept, however, has merit precisely because it allows deviation from the radiation protection standards which are, indeed, designed to be applicable to all. The attempt to specify by regulation what is 'least practicable' appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential, and yet removes from those subject to the regulation the responsibility for ascertaining what need be done to meet the 'least practicable' criteria."

The NCRP has no particular reason to complain about the use of low levels of radiation exposure such as proposed by the EPA and the NRC for light water-cooled reactors. It does, however, complain about the issuance of these new control numbers under the guise of the ALAP principle. Regardless of how they are described, and perhaps restricted to certain situations, these numbers nevertheless become identified as exposure "standards". The result of this is a complicated and almost meaningless matrix of standards, many of which are impractical or impossible of direct maintenance. Moreover the use of such numbers has a strong tendency to lull the consciousness of the radiation user into failing to meet the need to be continuously alert and responsible in radiation protection matters.

It should also be reemphasized that however low the present control numbers may be, and whatever they may be called, there is no reason why the basic numbers for radiation workers and the population need to be reduced.

Additionally, once such numbers have been generated and become "official" through publication in the Federal Register or other means, it is politically impossible to raise them at some time in the future should circumstances indicate the need. Once such numbers have been cranked into the dogma of radiation protection standards, they become monolithic. I can well visualize the time when, for good reasons and with reasonable safety, it may become necessary to adjust some of these numbers upward.

RECOMMENDATIONS

To deal with the misuse of the principle of "as low as practicable" we recommend:

(a) Adherence to the basic maximum permissible dose levels or dose limits established by the NCRP or the ICRP and contained in their most recent publications.

(b) As an alternative to (a) above, that some government agency come right out, frankly and honestly, and change the standards on a justifiable biomedical and political basis.

(c) Use of the conventional, industrial procedure of working at radiation levels that are lower than the basic permissible limits but allowing some judgment in the degree to which lower working levels may be employed.

(d) Retention of the intended flexibility of the principle of maintaining radiation exposure levels as low as practicable.

(e) Stop hiding oppressive radiation control numbers under the subterfuge of ALAP or other new names of new definitions that may crop up.

(f) Recognize a structure of basic radiation protection standards for workers and the population, noting that such a structure now exists and is in use the world over.

B. Transfer of FRC to a Single Agency

The second broad area of concern has been the transfer of the responsibilities of the Federal Radiation Council, as established in 1959, to a single federal agency which must live and operate in parallel with many other federal agencies having legitimate concerns with health and safety in the field of ionizing radiation.

(1) Bureau of the Budget Study

In the late 1950's it was recognized, as a result of hearings by the Joint Committee on Atomic Energy, that the federal government had no mechanism for establishing radiation protection standards and had always been in the position of having to accept those developed by the NCRP (then the National Committee on Radiation Protection). The problem was studied in depth by Dr. Robert Cutler in the Bureau of the Budget in 1959. The concept of establishing this responsibility within any single federal agency was examined and completely rejected. In addition to discussions with various agencies and outside groups, the matter was considered by the NCRP and I was personally very deeply involved in many of the discussions. This involvement was such that an agreement had been reached with the President's Science Advisor at that time, that the Executive Order would not be signed until I had approved it. (It so happened that I was in Europe at the time they wished to release the statement establishing the Federal Radiation Council and was consulted by telephone by Drs. Killian and Kistiakowsky relative to the specific language of the Executive Order. After the FRC was established, I became a member of its working group and from time to time an acting member of the FRC itself acting on behalf of the Secretary of Commerce.)

The major findings of the Cutler study at that time included:

(*a*) No one agency could provide the breadth of coverage needed for the development of radiation protection standards.

(*b*) No one agency could be assured, in the field of radiation protection, of adequate cooperation by all other concerned agencies.

(*c*) Interagency committees in the normal sense were traditionally ineffective and frequently served only for window dressing.

(*d*) Bureaucratic "necessities" stimulate a kind of rivalry that is costly and inefficient.

The original objectives assigned to the Federal Radiation Council were to adopt or develop protection standards needed by the federal government to carry out its individual federal responsibilities. This was needed because (as noted above) of the discovery that up until then the federal government had been in a position of having to essentially accept the standards recommended by a body (the NCRP) over which it had no control. This was clearly recognized by the government as well as by the NCRP as an untenable situation.

A critically important feature of the FRC was its mode of operation. The FRC itself was composed of Departmental Heads (Cabinet Officers), but each in turn assigned one of his top radiation experts to a "working group" that met weekly. It was their responsibility to consider the technical details and endeavor to reach agreement among the several agencies represented. This was then modified or stamped with approval by the most senior officers in the government. It was a stamp of authority that could not be achieved were the FRC in any single agency.

In its first activity after its formation in 1959, the Council made an intensive study of permissible dose standards. This study drew in representatives from government agencies, government laboratories, and many parts of the public sector—individuals with established reputations of knowledge and experience bearing on the subject. Following this intensive study, the FRC in its Report No. 1 adopted as basic standards for government use those that had been recommended by the NCRP and were already in use throughout the country. However, by this action on the part of an established government body, what had always been "recommendations by the NCRP" thenceforward became the standards of the U.S. Government for U.S. Government use.

It was an excellent example of the system of checks and balances that can evolve through close cooperation between the government and private bodies.

When the Environmental Protection Agency (EPA) was established by Executive Order, the functions of the FRC were transferred to the new organization without any change in the language from the original Executive Order EO–10881 or the subsequent amendment to the Atomic Energy Act of 1954. At the time that the reorganization and formation of the EPA was taking place, the Joint Committee on Atomic Energy had important reservations regarding the transfer of the original language into the new reorganization bill. (Adoption by reference). The JCAE prepared some alternate proposals. However, these were too complicated and would have involved too heavy a legal commitment by the National Council on Radiation Protection and the National Academy of Sciences to work with a federal agency.

While there were some features of the JCAE proposal that were desirable, the overall plan was basically opposed by both the NCRP and the NAS and never came to a critical issue.

(2) EPA Responsibilities from FRC

As I see the situation today, I feel that the EPA has grossly overextended its interpretation of the FRC responsibilities to positions that are far beyond the original objectives which applied to the federal government only. I believe that the proper interpretation of the original intent in the establishment of the FRC is clearly shown by the eight FRC reports which were issued prior to the establishment of the EPA.

Among improper areas of concern to the EPA are those in the general area of medical practice, patient dose limitation, shielding in medical installations, occupational exposures, etc. In this connection, the EPA has openly stated their intention to extend their areas of concern to non-governmental medical practice by their own interpretation that any services reimbursed by Medicare automatically fall within the FRC scope of "government needs". It is difficult also to see how any such interpretation can fall within the structure of "environmental protection". Their attitude toward using Medicare as a lever for government control shows a clear recognition of the fact that some kind of subterfuge was needed to support their extension of the stated FRC objectives. The EPA inclusion of general medical radiological procedures, either under FRC or environmental protection philosophy, overtaxes the imagination.

Such interpretation would place any regulatory, advisory, or control responsibilities in an organization and atmosphere that is professionally and intellectually mal-suited to the prbolem. If radiological practice, because it touches upon such a large fraction of the population, can be described as environmental—then so can practcially every other profession or business.

C. Existing Agency Role in Radiation Protection

(1) Environmental Protection Agency

The Environmental Protection Agency has a large, proper, and important role in the management of ionizing radiation in the environment. This would include such areas as radioactive contamination from uranium mill tailings or the manufacture of radioactive components, fallout from an accident or weapons testing, management of a radiation surveillance network, radioactive byproducts from industrial operations—such as mining of phosphates—etc., etc., etc.

The intellectual and professional atmosphere of EPA is well adapted to meet such responsibilities, but not those required for the development of basic radiation protection standards. The proper atmosphere within which they must operate is not conducive to attracting and holding the kind of professional competence needed—even if it were considered proper—to deal with that part of the radiation control problem.

EPA has a small dedicated staff that can manage the problems properly categorized as "environmental" by any argument and they should be encouraged to do the job. They should not attempt to justify or carry out responsibilities for radiological practice in the private (or possibly even in the government) sector. It can well be argued that what the medical profession does is none of the business of environmentally-oriented organizations unless they—the medical profession—start scattering radioactive material around in the public domain. It might reasonably be argued that, to the extent that *any* federal government agency has *any* responsibility in impinging upon *any* phase of private medical practice, this should be through the Food and Drug Administration or one of its bureaus such as the Bureau of Radiological Health.

(2) Bureau of Radiological Health

I will turn now to the role of the health agencies in the field of radiation protection. The role of the Food and Drug Administration (FDA) and its Bureau of Radiological Health (BRH) is much better developed through many years of organization and effort and—I suppose it should be added—turmoil. In my discussion below, I shall be thinking mainly in terms of the Bureau of Radiological Health—although its relationships to the FDA itself and to other bureaus of the FDA are recognized.

Within various organizational structures, and off and on for four decades, BRH has provided an intellectual and professional atmosphere reasonably well suited to dealing with radiation protection and health problems. These would relate well to radiation in medical practice and possibly to radiation used in industrial practice.

They have a clearly defined mission under the Health and Safety Act of 1967, and on the whole seem to be meeting it. If there are any major faults here. I believe they lie in the detail and the rigidity of the Act itself which all too often is a fault in any regulatory legislation. There may be a subsidiary fault (but I'm not sure that it applies yet to the BRH) that once the original objectives of a regulatory agency have been more or less met, the agency tends to go stale. The normal bureaucratic remedy for this is to find some new objectives so as to justify some new staff. New objectives frequently are met by stepping up detail and picking smaller nits.

I expect that we shall begin to be able to see this at BRH before too much longer. They are already in the adolescent period of some fifteen years of age, although they have only operated under the Health and Safety Act for half of that time.

The Health and Safety Act of 1967 was passed after extensive hearings (S-2067 and HR-10790). It was not recognized then, but is now, that two or three major lines of testimony were in gross error, or subject to exaggeration or bias. It is barely possible that without this distortion, even though some was unintentional, the original act might not have been passed in its present form and with its present emphasis. Distorted testimony or not, I believe that the BRH meeting of its responsibilities has been a net plus, although we are certainly not in a position to argue its cost-effectivenes, one way or the other.

The biggest blunder in the testimony in 1967 was the PHS calculation of a genetrically significant dose resulting from the diagnosis medical application of x-rays. They then presented a figure that subsequently was found to be some

2½ to 3 times too high and hence far out of line with comparable figures for other advanced countries. Their figure and the malalignment with those of other countries was played upon extensively by witnesses other than those directly associated with the Public Health Service. The figures for the genetically significant dose (GSD) as given should have been cause for alarm had they been correct. Its ultimate result was in the introduction of costly corrective measures through the introduction of special x-ray equipment requirements. These measures were not only costly to medical care and the patient, but in most instances the gain was almost trivial. It may now be justified to do away with one particular corrective measure which was introduced in an attempt to reduce the G.S.D. to the level which we no recognize it already was. I am referring to the automatic collimation system. the installation of which has been particularly burdensome to the many relatively small x-ray diagnostic installments which are nevertheless critical to health care. I believe that the BRH is now considering some relaxation of this early requirement.

Another example might be the proposal, in the search for safety, to overplay some relatively minor factors such as reduction of the leakage radiation from low voltage therapy tubeheads from one R per hour to one-tenth R per hour. This doesn't sould like much, but it involves 3 extra half value layers of lead that is to be placed in the tube container—plus the same weight in the counter balance, plus the added weight of the structure to support the first two wieghts. All of this adds to the bulkiness and cost of the equipment and at the same time detracts from its flexibility. The reduction of patient exposure is unimportantly small in comparison with the scattered radiation from the treatment itself, for which there is no avoidance. No personnel is in the room with the patient during treatment. I have not tried to find out where this proposal stands, but I cite it as an example of what may be trivia.

Testimony presented by individuals outside the HEW in 1968 was extensive. I do not know how much of it was voluntary or solicited. However, some of the testimony dwelt at length and depth with horrendous calculations of the deaths being caused by the diagnostic x-ray practices. They were truly terrifying until you examined the underlying information and assumptions. As it turned out, they were based largely on bizarre assumptions, misleading and obfuscating presentations, and were never borne out by established facts. No one has ever taken the trouble to refute this testimony, probably because it was so entangling and would become a job that would be too time-consuming and detractive from useful enterprise. In any case, it has served its "purpose" and cannot really be undone, however mischievous it might have been.

The Bureau of Radiological Health now has substantial regulatory responsibilities and maintains a laboratory capability for dealing with whatever associated technical demands may arise. In some of these areas the engineering complexities seem to overshadow the straight health or biomedical aspects of the problem. Nevertheless, their laboratory capability is adequate. From a taxpayer's viewpoint I have wondered about their making more use of the National Bureau of Standards' existing facilities which are backed up by an overall staff dealing with dosimetry and instrumentation for ionizing radiation that cannot be matched. The BRH already uses the NBS to some extent—whether to an optimum amount or not I have not tried to determine.

An unsurpassed asset of the PHS/FDA/BRH complex is the fine corps of "graduates" that they have in every state of the union. Through the Commission Corps operation, many highly capable men retire after twenty years of service and move into state and other health channels. This provides an invaluable two-way system for feeding information in and spreading reaction out from the Federal agency. This provides a unique mechanism enabling the Federal Government to communicate into the core of the State health community. The only potential misuse of this that I see is the possibility of developing a well-orchestrated reaction to some situations based more on political or bureaucratic angles than on the real needs for public health.

(3) Nuclear Regulatory Commission

Turning now to the Nuclear Regulatory Commission, the main problem that I see has to do with possible overreaction to public demands for nuclear safety. The public fails to recognize that absolute safety does not exist in this world. The NRC should perhaps put more of its effort into some kind of educational programs promoting the concept of an "acceptable risk." For that matter, so should the other agencies involved in radiation matters.

The NRC (and frequently the EPA) are plagued with what can only be described as nuisance or obstructive suits centering about their radiaton protection practices. Reaction to some of these in recent times must have cost the taxpayers millions of dollars. In addition, these suits have wasted, literally wasted, countless thousands of man-hours of some of our best radiation protection talent. They have diverted hundreds of hours of valuable time of individual participants working through the NCRP who are not being paid by the Government in the first place. Now there is talk of the government underwriting the cost of these obstructive tactics, a large porportion of which are without any semblance of technical validity. We hope that Congress somewhere, can (in its infinite wisdom) find some solution to this overbearing problem.

(4) Energy Research and Development Administration

Turning next to the Energy Research and Development Administration, I must say that in our experience this organization has an enviable track record in the overall area of health and safety. If they have any critical problems in the field of ionizing radiation, they do not seem to have impinged on the NCRP consciousness except as noted below. ERDA must have not only the world's finest stable of scientists and engineers in the radiation and nuclear fields, but also the finest stables within which to work. In addition, they manage to seduce into their Washington headquarters a management staff of experience and dedication not easily matched in the normal bureaucratic process. This is a situation which will not automatically continue indefinitely. It needs to be understood and nurtured.

ERDA undoubtedly continues to suffer from their legacy from the AEC—having once had to live under the worst public relations handicap of modern times. This can only be overcome by encouraging and supporting the agency to play the situation straight whatever the appearances. By this means they may be able to outlive their unfortunate legacy.

A possible problem to watch for in ERDA's future—as far as radiation is concerned—is to insure that not too much of its nuclear capability is diverted to other energy programs. The other programs are needed and the existing staffs can play important roles in solving the problems. But if we dissipate our nuclear competence, it will be most difficult to restore it adequately to meet the future needs that are absolutely certain to arise. It might be noted also that there is increasing concern over the diminishing crop of graduates, as well as research opportunities, in the general field of radiobiology. To a considerable extent this is due to cutbacks in ERDA and other research programs, such as through NIH, NSF, etc. This may seem to represent the proper choice of priorities at the moment, but radiobiology should not be allowed to decline just by default. Also training programs in this area need to be encouraged and supported. Of special need are multidisciplined persons trained as well in radiobiology.

(5) Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) has no competence in the field of ionizing radiation. They believe they have a mission in radiation control, but it is obviously of such low priority that it cannot accomplish anything useful. I do not see any part of their mission which could not be better done by any of several other federal agencies. Also, their involvement leads to duplication of regulations and regulatory personnel.

(6) Department of Transportation

The Department of Transportation has a clear mission in the safety of transport of nuclear materials. We are not in a position to comment constructively upon it. From discussion with members of the Air Line Pilots Association (ALPA), from time to time, we get the impression that the Department of Transportation/Federal Aviation Administration rules and regulations for the movement of radioactive materials are satisfactory, but their enforcement is far from adequate. DOT seems to have the necessary professional competence to deal with the basic problems, but they do not have the staff, and possibly not even the authority, to properly control the situation.

III. *Possible Solutions for Some Problems*

Having directed attention to what may be some problem areas in several of the federal agencies concerned with radiation safety, it would be appropriate to consider some possible solutions. Some of these have already been considered from time to time.

A. *Single New Agency*

Recognizing the complex matrix of government interest in radiation health and safety, one proposal has been to establish a new single agency to set standards and develop the corresponding regulations (for government use only) and to organize any needed enforcement capability. Upon consideration, it appears to be impractical to form any *new* agency that could acquire the needed professional competence and proper working atmosphere to accomplish the overall objective above. Consider the varied, and often conflicting, interests of Defense, HEW, Agriculture, Medicine, Labor, etc. All you have to do is to look at the various splinter operations that have developed in the federal government over the past two decades. Building up a new agency by cannibalizing from other agencies (such as ERDA, NRC, BRH) only removes pieces from successful operating organizations with a good overall competence and proper working atmosphere. Moreover, the chances of acquiring the best staff members for such a new organization are regarded as extremely remote. There are too many better and more challenging opportunities available outside of the government. Again, look around. Good, working organizations will be destroyed only to generate poor new organizations.

As we look around at the assortment of radiation protection activities scattered through the federal government, the theory of placing them all in a single organization looks good, but we are convinced that the result would be as least as disastrous, and probably more so, as the situation we now have.

B. *Reactivation of the FRC*

A second solution for at least part of the problem is to reestablish the Federal Radiation Council outside of my individual agency. In doing this, one should consider the modification of the working rule in the old FRC that always required absolute unanimity upon the agency members. At times this might be an asset, but sometimes it was an absolute roadblock to progress.

Whatever the structure, the FRC should be organized at a level above the departmental level and in the Executive Office if necessary. Perhaps the solution here would be to place the FRC in the Executive Office in principle but make it possible for the FRC to operate on the basis of departmental acceptance of decisions and official agreements. With this arrangement, the Executive Office itself would be used only in the cases of necessary adjudication in those rare instances of stalemate. The existence of an executive adjudication step would probably largely eliminate any stalemate situations.

A basic policy would be that any new Federal Radiation Council actions would apply only to government operations. Any applications of FRC actions to such areas as the private practice of medicine, industry, education, etc., would be through some strictly non-federal process.

A positive step should be taken to stop the current technique of managing the private sector through subterfuge and indirection. States or other levels of government should be completely free to choose what they wish to use from the federal patterns, but be free from pressure or coercion, except when uniformity of standards would be critical and involve interstate considerations, e.g., air, water, and food contamination or protection requirements for some commercial products. There would obviously have to be some mechanism to insure the necessary compliance with federal standards for such operations as nuclear power. I believe it has already been decided that the federal standards in this area preempt those of the states.

C. *Single Existing Agency*

If any one agency were to be given the responsibility for the development of overall radiation protection standards, it should probably be ERDA for one principal reason: ERDA probably possesses the greatest overall competence in biology, medicine, physics, chemistry, engineering, epidemiology, mathematics, etc.—all of which are critical parts of the radiation protection picture. In addition, as already noted, ERDA already manages the world's finest laboratories in the nuclear and radiation field.

Probably the next best choice would be the Bureau of Radiological Health, again on the basis of staff competence, work atmosphere, and a long heredity in the field of health and safety. On the other hand, BRH may not be sufficiently broadly based in other areas of science and technology to take on the full responsibility for developing radiation protection standards. It might be advantageous for the BRH to divest itself of some of its regulatory responsibilities and concentrate more on basic science. Regulatory responsibilities are time consuming and very costly, and are frequently incompatible with a high intellectual atmosphere.

BRH has the very great advantage of high motivation in the field of health. On the other hand, it lacks some of the needed competence outside of the strictly health area. It is gradually acquiring this competence, but it is not easy to attract the highest level of, say, physical scientists into the health science surroundings. This has always been a problem with HEW organizations such as BRH, NIH, etc.

The NRC is established primarily for regulatory purposes and as such has a good professional staff. However, it lacks working atmosphere and laboratories which are frequently necessary to attract some of the high caliber personnel that may be required. They do make good use of other government laboratories, but it is not the same as having their own.

The National Bureau of Standards should be one of the most unbiased and independent of the federal agencies. It has no regulatory responsibilities. It could manage a function such as a Federal Radiation Council. Its big advantage here would be the absence of any vested interest. The NBS lacks its own health and biomedical capability, but it is strong in other areas of interest here. It might be noted that they did indeed manage the development of the first FRC standards through the extended study I mentioned above.

D. *Delaney Amendment*

In conclusion of this portion of my testimony, I would like to direct your attention to a situation with which your Committee must almost certainly be cognizant. That situation centers about he Delaney Amendmen of some years ago. For all of its good intentions, the Delaney Amendment is so rigidly written and interpreted as to play upon the fears of the public, centering about the cause of cancer. Without going into detail, let me mention that the Delaney Amendment already restricts radiation uses in the food and drug industry to the point of depriving the public of extremely important radiation application in the food and drug industry. The risk—which has never been proved—is extremely small compared with any other kind of risks that you should wish to use for comparison purposes. That the amendment expresses a fine principle cannot be denied, but in practice it is too rigid and restrictive and it is out of touch with reality. This is again an excellent example of why the public has to be educated to accept some risk and to abandon the fallacious concept of a zero risk philosophy.

More attention should be paid to the Palooka Principle (c.f. Newsweek *89*, 11, 13 June 1977).

[The following information was received for the record:]

QUESTIONS OF THE COMMITTEE AND NCRP RESPONSES

Question 1. Please review your current programs and identify for the Committee the issues which you perceive are in need of resolution. This discussion may include those issues which appear to be of immediate consumer concern or those issues which are relevant to a clarification of federal agency responsibility. They may include your views as to needed revisions in existing legislation, initiation of research, education and training, state and federal cooperation, transportation, materials handling, disaster response, inspection or certification of devices, and other similar issues.

Question 2. Please describe the inter-relationships of your group with industry groups, federal and state governments, international organizations, academic institutions, and other groups with regard to the development of standards and/or research activities.

Question 3. Has any current research been identified by your group as deserving special attention?

Question 4. What are the Council's views as to the adequacy of present non-ionizing and ionizing radiation standards (both exposure and emission standards)?

Question 5. What is the Council's position with regard to the proposals to reduce present individual and population exposure standards to a level such as those set by the Eastern Europeans?

Question 6. What is the Council's reaction to proposals that individual dosimeters be required for all workers engaged in radiation work or otherwise subjected to exposure?

Question 7. What is the Council's reaction to proposals that individual medical records be required to include all information on exposure received in diagnostic or clinical radiology?

Question 8. What is the Council's reaction to the proposals that (1) radiologic technicians be licensed and certified to meet either state or federal standards and (2) that radiation health and safety responsibilities within the Federal government be clarified and/or centralized?

Answer 1A. The work of the NCRP is primarily through committee actions, each of which is designed to study a prescribed aspect of a problem in radiation protection or radiation measurement. Currently, the NCRP has some 58 Scientific Committees and 8 Ad Hoc Committees. At any one time, roughly two thirds of these committees are active. The remaining committees may be in some form of stand-by status. Attached is a current list of the NCRP Committees (Item 1).

The output of the NCRP is in the form of published reports as prepared by individual committees and reviewed by the full elected membership of the Council. The general procedure is for the Board of Directors to define and assign a particular problem to a committee. Any committee membership must be approved by the Board and the full committee must contain an adequate balance of expertise for the assignment. Upon completion of a report by a committee, it is first reviewed in depth by "critical reviewers" chosen from the NCRP membership as being most knowledgeable in the particular area covered by the report, (they are not, however, committee members). Each report is then subject to review by the 75 elected members and any objections must be resolved before the report is published. It is important also that no individual or organization outside of the NCRP has the power of either suppressing or releasing a report. That is the sole prerogative of the Council. Attached is a list of the reports published to date together with some half dozen which are currently in press, (Item 2). Another half dozen are approaching completion through review process.

Answer 1B. Outstanding issues for which we see the need of resolution would be, a) the misuse of the principle of "as low as practicable" and b) a reevaluation of the role and organizational location of what used to be the Federal Radiation Council. The following are comments on this question:

"The implications arising from the attempted use of the 'least practicable' concept in regulations are of concern to the NCRP. It is generally accepted that laws or regulations should be uniform in their application to all within their jurisdiction. Indeed this is one of the prime virtues of laws or regulations. The 'low as practicable' concept, however, has merit precisely because it allows deviation from the radiation protection standards which are, indeed, designed to be applicable to all. The attempt to specify by regulation what is 'least practicable' appears to be an unfortunate melding of concepts which vitiates the merits on each side. It undoes the assured uniformity of regulations because deviation on a case-by-case basis would appear essential, and yet removes from those subject to the regulation, the responsibility for ascertaining what need be done to meet the 'least practicable' criteria".

Answer 1C. Many radiation protection practices may be of consumer concern. An NCRP report (No. 56) now in press, deals with a wide range of situations involving radiation exposure of the public from consumer products. We do not see any particular problems here which require resolution. It is largely a matter of identifying the problem and then developing some recommendations for solving it. This is not to imply that there are no problems, but we do not see any of them requiring Congressional consideration.

Answer 1D. There are broad problems relative to individual federal agency responsibilities and some of these are discussed separately.

We do not see any crying needs for new legislation in the field of radiation health and safety. If anything, we would probably feel that there is already too much legislation. There are other hazards which are much more severe than those form ionizing radiation and it is of importance that there be some suitable balance of effort in attacking the various insults to which man is subjected. It should not be forgotten that up to the present time there are no known cases of radiation injury to individuals who have been exposed within the permissible dose levels for radiation workers. This is not to say that there have not been court or compensation awards for "radiation injury" in individual cases but these have been decided on a political or legal rather than scientific or medical basis.

For many years there was important government support for training and education in the field of radiation protection and measurements. These programs were carried out largely by the Atomic Energy Commission and the Department of Health, Education and Welfare. As a result of these programs, the United States probably has one of the finest cadres of radiation protection personnel of any country. It also has an unbelievably fine record for safety in the radiation industry which surpasses that of almost any other occupation. In recent years these programs have been cut out or cut back to the point where they are almost non-existent today. This is an enormous pity because the cost of the programs must be very small in comparison with the benefits that derive directly or indirectly from the people so trained. We believe that there should be some restoration of these training programs.

Answer 2. The National Council on Radiation Protection and Measurements has no strict inter-relationship with any outside organization or governmental unit. On the other hand, we have loose relationships with many organizations but only under such circumstances as may be conductive to leaving the NCRP with complete freedom and avoiding any kind of censorship or veto power.

The NCRP has, what is termed, collaborating relationships with some 30 organizations both from the private as well as the governmental sector. These relationships involve no control authority one way or the other, but they do provide a ready mechanism for input of ideas to the Council and output from the Council to the organizations. Some of these organizations make financial contributions to the NCRP but there is no necessary relationship between a collaborative and a contributing status. Attached is a list of the collaborating organizations (Item 3).

Probably our most important relationships with outside organizations comes through our membership. While none of our committee members or elected members of the Council officially represent any organization they nevertheless bring to the Council ideas and information generated because of their association with universities, laboratories, state governments, industry groups, etc. It is a basic principle of the NCRP that it should strive to avoid any direct involvement with, or commitments to, outside organizations which could have an overriding influence upon its recommendations. The Council scrupulously avoids any kind of relationship with an outside organization, including federal agencies, which may be regarded as "advisory". We produce recommendations, as already noted. These may be used by Agencies or not as they wish. The Agency receives its reports from the NCRP through the public domain the same as any individual. Measures such as these insure the objectivity of NCRP studies and reports and avoid even any semblance of pressure from outside groups.

Answer 3. The most important research that might lead to improvements in our understanding of radiation protection problems should be directed to the understanding of the basic mechanism of interaction between radiation and the living cell. While there is an enormous amount of such information available it is still incomplete and the fundamental process is not known sufficiently to answer all questions. It is, however, known to a degree sufficient to enable us to provide acceptable levels of protection for the radiation workers or the population that may be exposed within the dose limits that have been recommended for the past 40 years. However, the problem remains that radiation injury is "suspected" at levels below which no deleterious effect has ever been observed. This is a troublesome problem for radiation as it is for a host of other potentially injurious agents. The solace here is that the effects, if any, of very low doses of radiation delivered at very low dose rates are so few and so obscure as to be masked by the effects from the many other agents with which we live but which do not involve radiation. An understanding of the basic mechanisms might solve some of these annoying problems.

Another important area of research for which there appears to be a growing need has to do with the specific biological effects of neutrons and other high LET radiation. Today there is some evidence that neutrons may be more injurious in comparison with gamma-rays than has been thought in the past. While the number of people exposed to neutrons is very small, and limited primarily to industrial situations an understanding of the basic interactions has important implications in other directions. For example, if it turned out that we have been using an inadequate quality factor for neutrons as compared to low LET radiation, it could conceivably mean that high energy accelerators and certain fuel reprocessing operations could require costly additions in shielding.

Answer. 4. At the moment the Council has no sharply defined views as to the adequacy of the protection standards for non-ionizing radiation. It has two committees working on this subject, the first dealing with the necessary quantities and units with which microwave radiation may be properly measured. The second has to do with the biological effects of microwave radiation. Here again, the issue is clouded by the fact that the measurement problem is not in an adequately satisfactory condition. It is further clouded by the fact that no biological effects of real significance have been observed except at extremely high levels of microwave intensity. Here again it should be pointed out that there are no known cases of injury due to microwave levels which are currently regarded as acceptable in this country.

With regard to the standards for ionizing radiation the NCRP is satified with their present status as contained in NCRP report No. 39 and any subsequent reports. These standards, which have been under continuous study by the NCRP and its predecessor organizations for nearly 50 years are considered acceptable by qualified experts in the field. Lower levels of radiation as prescribed, for example, for certain types of power reactors are good for the particular situation but they could be very much higher if there was any reason for raising them. See the extended testimony for further details.

Answer 5. As far as we are aware, the x-ray standards used by the Eastern European countries are basically the same as those in the United States although they are sometimes expressed somewhat differently. For microwave radiation the standards appeared to be more severe by a factor of at least 10 but there are no known data indicating the proven necessity for this.

Answer 6. The Council would not endorse the proposal that individual dosimeters be required for all workers engaged in radiation work or otherwise subjected to exposure. The following statement from paragraph 219 in our report No. 39 covers this point:

"The NCRP has stated previously that personnel monitoring shall be performed for each occupationally exposed individual for whom there is a reasonable possibility of receiving a dose exceeding one-fourth of the applicable MPD [25]. Such a statement properly implies that accurate dose equivalent determinations below one-fourth of the MPD are not required".

In the first place the use of individual dosimeters serves primarily as an indication of the adequacy of a safety program. Except for accident situations, the readings from them are of virtually no use in so far as an evaluation of radiation effects may be concerned. The use of individual dosimeters for everybody is simply a costly nuisance. There are many situations where radiation levels cannot, even through accident, increase above a certain level. If this is less than a quarter of the appropriate permissible does, area monitoring without individual dosimeters can be entirely adequate.

Answer 7. There can be no reasonable opposition to the maintenance of individual medical records but the degree to which the radiation dose may be recorded is subject to interpretation. For record purposes and diagnostic procedures it is usually adequate to simply record the kind of examination or field of exposure, the number of exposures, etc. Calculations or measurements of the dose are subject to gross inaccuracies under the best of conditions. We see little purpose and great expense in such a procedure. The kind of dose information obtained would be of no value, except under possibly a few limited circumstances, in evaluating radiation effects or radiation injuries or even poor practice in radiological procedures.

Answer 8(a). The Council has not had occasion to develop any particular position regarding a licensing or certification of radiological technicians and perhaps some certification procedure would help to sort them out. On the other hand, the primary responsibility for any diagnostic procedure is in the hands of the concerned physician specialist and it is *his* responsibility to be assured that the technician can perform his wishes properly. I suspect that our philosophy on this question would be largely conditioned by our basic philosophy that licensing, certification, regulating or legislating, in the field of radiation protection should be kept to an absolute minimum. We recognize that it cannot be avoided entirely. Regulation is approaching the point of becoming an unbearable burden on society.

Answer 8(b). There is a wasteful matrix or radiation related responsibilities in the federal government but we are not convinced that the solution to this problem is by centralization. Much can be done to clarify the missions of a number of the agencies and probably some agency responsibilities can be eliminated.

(6) Department of Transportation

The Department of Transportation has a clear mission in the safety of transport of nuclear materials. We are not in a position to comment constructively upon it. From discussion with members of the Air Line Pilots Association (ALPA), from time to time, we get the impression that the Department of Transportation/Federal Aviation Administration rules and regulations for the movement of radioactive materials are satisfactory, but their enforcement is far from adequate. DOT seems to have the necessary professional competence to deal with the basic problems, but they do not have the staff, and possibly not even the authority, to properly control the situation.

POSSIBLE SOLUTIONS FOR SOME PROBLEMS

Having directed attention to what may be some problem areas is several of the federal agencies concerned with radiation safety, it would be appropriate to consider some possible solutions. Some of these have already been considered from time to time.

A. Single New Agency

Recognizing the complex matrix of government interest in radiation health and safety, one proposal has been to establish a new single agency to set standards and develop the corresponding regulations (for government use only) and to organize any needed enforcement capability. Upon consideration, it appears to be impractical to form any *new* agency that could acquire the needed professional competence and proper working atmosphere to accomplish the overall objective above. Consider the varied, and often conflicting, interests of Defense, HEW, Agriculture, Medicine, Labor, etc. All you have to do is to look at the various spliner operations that have developed in the federal government over the past two decades. Building up a new agency by cannibalizing from other agencies (such as ERDA, NRC, BHR) only removes pieces from successful operating organizations with a good overall competence and proper working atmosphere. Moreover, the chances of acquiring the best staff members for such a new organization are regarded as extremely remote. There are two many better and more challenging opportunities available outside of the government. Again, look around. Good working organizations will be destroyed only to generate poor new organizations.

As we look around at the assortment of radiation protection activities scattered through the federal government, the theory of placing them all in a single organization looks good, but we are convinced that the result would be at least as disastrous, and probably more so, as the situation we now have.

B. Reactivation of the FRC

A second solution for at least part of the problem is to reestablish the Federal Radiation Council outside of any individual agency. In doing this, one should consider the modification of the working rule in the old FRC that always required absolute unanimity upon the agency members. At times this might be an asset, but sometimes it was an absolute roadblock to progress.

Whatever the structure, the FRC should be organized at a level above the departmental level and in the Executive Office if necessary. Perhaps the solution here would be to place the FRC in the Executive Office in principle but make it possible for the FRC to operate on the basis of departmental acceptance of decisions and official agreements. With this arrangement, the Executive Office itself would be used only in the cases of necessary adjudication step would probably largely eliminate any stalemate situations.

A basic policy would be that any new Federal Radiation Council actions would apply only to government operations. Any applications of FRC actions to such areas as the private practice of medicine, industry, education, etc., would be through some strictly non-federal process.

A positive step should be taken to stop the current technique of managing the private sector through subterfuge and indirection. States or other levels of government should be completely free to choose what they wish to use from the federal paterns, but be free from pressure or coercion, except when uniformity of standards would be critical and involve interstate considerations, e.g., air, water, and food contamination or protection requirements for some commercial products. There would obviously have to be some mechanism to insure the necessary compliance with federal standards for such operations as nuclear power. I believe it has already been decided that the federal standards in this area preempt those of the states.

NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

SCIENTIFIC COMMITTEES

(June 2, 1977)

SC–1: Basic Radiation Protection Criteria—G. W. Casarett, Chairman.
SC–1: Basic Radiation Protection Criteria—Task Group on Irradiation of the Fetus Resulting from Medical Care of the Mother—R. O. Gorson, Chairman.
SC–2: Permissible Internal Dose*
SC–3: Medical X- and Gamma-Ray Protection Up to 10 MeV (Equipment Design and Use)—E. C. Gregg, Chairman.
SC–4: Heavy Particles (Neutrons, Protons and Heavier)*—H. H. Rossi, Chairman.
SC–5: Electrons, Gamma Rays and X-Rays Above Two Million Volts*—H. W. Koch, Chairman.
SC–6: Safe Handling of Radioactive Materials*—J. W. Healy, Chairman.
SC–7: Monitoring Methods and Instruments—E. W. Webster, Chairman.
SC–8: Waste Disposal and Decontamination.*
SC–9: Medical X- and Gamma-Ray Protection Up to 10 MeV (Structural Shielding Design)—J. P. Kelley, Chairman.
SC–10: Regulation of the Radiation Exposure Dose.*
SC–11: Incineration of Radioactive Waste—G. W. Morgan, Chairman.
SC–12: Electron Protection*—E. G. Fuller, Chairman.
SC–13: Safe Handling of Bodies Containing Radioactive Isotopes*—E. H. Quimby, Chairman.
SC–14: Radiological Factors Affecting Decision Making in a Nuclear Attack—G. W. Casarett, Chairman.
SC–15: Radiation Protection in Teaching Institutions*—F. J. Shore, Chairman.
SC–16: X-Ray Protection in Dental Offices—R. J. Nelsen, Chairman.
SC–17: Veterinary X-Ray Protection*—B. F. Trum, Chairman.
SC–18A: Standards and Measurements of Radioactivity for Radiological Use—Standards Procedure Section—W. B. Mann, Chairman.
SC–18B: Standards and Measurements of Radioactivity for Radiological Use—Medical and Biological Applications Section—W. J. MacIntyre, Chairman.
SC–19: Standards and Measurement of Radiological Exposure.*
SC–20: Standards and Measurement of Absorbed Radiation Dose.*
SC–21: Relative Biological Effectiveness*—V. P. Bond, Chairman.
SC–22: Radiation Shielding for Particle Accelerators—E. A. Burrill, Chairman.
SC–23: Radiation Hazards Resulting from the Release of Radionuclides into the Environment—W. S. Snyder, Chairman.
SC–24: Radionuclides and Labeled Organic Compounds Incorporated in Genetic Materials—E. P. Cronkite, Chairman.
SC–25: Radiation Protection in the Use of Small Neutron Generators—W. C. Roesch, Chairman.
SC–26: High Energy X-Ray Dosimetry—R. J. Shalek, Chairman.
SC–27: Specification of Radium Substitutes*—M. M. D. Williams, Chairman.
SC–28: Radiation Exposure from Consumer Products—D. W. Moeller, Chairman.
SC–29: Brachytherapy—E. L. Saenger, Chairman.
SC–30: Physical and Biological Properties of Radionuclides—R. O. McClellan, Chairman.
SC–31: Selected Occupational Exposure Problems Arising from Internal Emitters—R. E. Rowland, Chairman.
SC–32: Administered Radioactivity—A. B. Brill, Chairman.
SC–33: Dose Calculations—W. S. Snyder, Chairman.

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*Inactive

SC–34: Maximum Permissible Concentrations for Occupational and Non-Occupational Exposure—J. N. Stannard, Chairman.
SC–35: Environmental Radiation Measurement—J. E. McLaughlin, Chairman.
SC–36: Tritium Measurement Techniques for Laboratory and Environmental Use—W. C. Reinig, Chairman.
SC–37: Procedures for the Management of Contaminated Persons—G. L. Voelz.
SC–38: Waste Disposal—Task Group on Krypton-85—M. Eisenbud, Chairman.
SC–38: Waste Disposal—Task Group on Carbon-14—A. A. Moghissi, Chairman.
SC–38: Waste Disposal—Task Group on Tritium—M. Eisenbud, Chairman.
SC–38: Waste Disposal—Task Group on Iodine-129—L. K. Bustad, Chairman.
SC–39: Microwaves—G. M. Wilkening, Chairman.
SC–40: Biological Aspects of Radiation Protection Criteria—A. C. Upton, Chairman.
SC–41: Radiation Resulting from Nuclear Power Generation—G. H. Whipple, Chairman.
SC–42: Industrial Applications of X Rays and Sealed Sources—F. L. Paschal, Chairman.
SC–43: Natural Background Radiation—J. H. Harley, Chairman.
SC–44: Radiation Associated With Medical Examinations—R. D. Moseley, Jr.
SC–45: Radiation Received by Radiation Employees—G. B. Hutchison, Chairman.
SC–46: Operational Radiation Safety—C. Meinhold, Chairman.
SC–47: Instrumentation for the Determination of Dose Equivalent—H. O. Wyckoff, Chairman.
SC–48: Apportionment of Radiation Exposure—W. K. Sinclair, Chairman.
SC–49: Radiation Protection Guidance for Paramedical Personnel—E. H. Quimby, Chairman.
SC–50: Surface Contamination—J. W. Healy, Chairman.
SC–51A: Radiation Protection in Pediatric Radiology—A. K. Poznanski, Chairman.
SC–51B: Radiation Protection in Pediatric Radiology Applied to Children—A. E. James, Chairman.
SC–52: Conceptual Basis of Calculations of Dose Distribution——.
SC–53: Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Radiation—A. W. Guy, Chairman.
SC–54: Bioassay for Assessment of Control of Intake of Radionuclides—H. F. Schulte, Chairman.
SC–55: Experimental Verification of Internal Dosimetry Calculations—J. S. Robertson, Chairman.
SC–56: Scientific Committee on Mammography—L. H. Hempelmann, Chairman.
SC–57: Scientific Committee on Internal Emitter Standards—J. Newell Stannard, Chairman.
Acceptable Risk Study Group (Nuclear Waste)—F. Seitz. Chairman.
Ad Hoc Committee on Comparison of Radiation Protection Philosophies—G. W. Casarett, Chairman.
Ad Hoc Committee on Hot Particles—W. J. Bair, Chairman.
Ad Hoc Committee on Internal Emitter Activities, W. J. Bair, Chairman.
Ad Hoc Committee on NCRP Procedures—R. S. Caswell, Chairman.
Ad Hoc Committee on Radioactivity in Drinking Water, S. Warren, Chairman, J. Newell Stannard, Co-Chairman.
Ad Hoc Committee on Thyroid Blocking, E. L. Saenger, Chairman.

Report Number and Title

8—Control and Removal of Radioactive Contamination in Laboratories.
9—Recommendations for Waste Disposal of Phosphorus-32 and Iodine-131 for Medical Users.
10—Radiological Monitoring Methods and Instruments.
12—Recommendations for the Disposal of Carbon-14 Wastes.
16—Radioactive Waste Disposal in the Ocean.
22—Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in Water for Occupational Exposure.
23—Measurement of Neutron Flux and Spectra for Physical and Biological Applications.
25—Measurement of Absorbed Dose of Neutrons and of Mixtures of Neutrons and Gamma Rays.

27—Stopping Powers for Use with Cavity Chambers.
28—A Manual of Radioactivity Procedures.
30—Safe Handling of Radioactive Materials.
32—Radiation Protection in Educational Institutions.
33—Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV—Equipment Design and Use.
35—Dental X-Ray Protecstion.
36—Radiation Protection in Veterinary Medicine.
37—Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides.
38—Protection Against Neutron Radiation.
39—Basic Radiation Protection Criteria.
40—Protection Against Radiation from Brachytherapy Sources.
41—Specification of Gamma-Ray Brachytherapy Sources.
42—Radiological Factors Affecting Decision-Making in a Nuclear Attack.
43—Review of the Current State of Radiation Protection Philosophy.
44—Krypton-85 in the Atmosphere—Accumulation, Biological Significance, and Control Technology.
45—Natural Background Radiation in the United States.
46—Alpha-Emitting Particles in Lungs.
47—Tritium Measurement Techniques.
48—Radiation Protection for Medical and Allied Health Personnel.
49—Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies up to 10 MeV.

Adjunct to Report 49

50—Environmental Radiation Measurements.
51—Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities.
52—Cesium-137 from the Environment to Man: Metabolism and Dose.
53—Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women.

To Be Published

54—Medical Radiation Exposure of Pregnant and Potentially Pregnant Women.
55—Protection of the Thyroid Gland in the Event of Releases of Radioiodine.
56—Radiation Exposure from Consumer Products and Miscellaneous Sources.
57—Influence of Dose and Its Distribution in Time on Dose-Effect Relationships for Low-LET Radiation.
58—A Manual of Radioactivity Measurements Procedures.

APPENDIX 4

COLLABORATING ORGANIZATIONS

(December 31, 1976)

American Academy of Dermatology
American Association of Physicists in Medicine
American College of Radiology
American Dental Association
American Industrial Hygiene Association
American Insurance Association
American Medical Association
American Nuclear Society
American Occupational Medical Association
American Podiatry Association
American Public Health Association
American Radium Society
American Roentgen Ray Society
American Society of Radiologic Technologists
American Veterinary Medical Association
Association of University Radiologists
Atomic Industrial Forum
College of American Pathologists

Defense Civil Preparedness Agency
Genetics Society of America
Health Physics Society
National Bureau of Standards
National Electrical Manufacturers Association
Radiation Research Society
Radiological Society of North America
Society of Nuclear Medicine
United States Air Force
United States Army
United States Energy Research and Development Administration
United States Environmental Protection Agency
United States Navy
United States Nuclear Regulatory Commission
United States Public Health Service

QUESTIONS FROM THE COMMITTEE FOR DR. LAURISTON TAYLOR

During your oral testimony you stated that EPA has grossly overextended its interpretations of the FRC responsibilities to positions that are far beyond the original objectives. If EPA ought not to be concerned about the areas which you mentioned, such as medical practice, patient dose limitation, shielding and medical installations occupational exposures, etc., which agencies appropriately should be?

During your oral testimony you stated, "The genetic reasons for having lowered the levels in 1956 were incorrect, and we could have left them alone." Please explain the basis for that statement, providing appropriate documentation when necessary.

During your testimony you stated that radiation treatments prescribed in the 1930's, "have not been linked to thyroid injury." The statement seems to conflict with other statements about the linkage between thyroid cancer and radiation. Please provide the Committee with the basis for the statements you made.

Please provide the Committee with the NCRP Committee report on radiation-emitting consumer products once it is available.

What research into the biological effects of radiation is currently being conducted by NCRP, and at what levels of support?

Your written statement to the Committee refers to the "possible over-reaction to public demands for nuclear safety . . ." by the NRC. In what areas may the NRC have over-reacted?

You suggest that reestablishment of the Federal Radiation Council in the Executive Office of the President might solve present interagency coordination problems. Doesn't OTP serve a coordinating function at least with respect to non-ionizing radiation now? How effective have OTP's efforts been?

In your testimony you indicated that certain features of the Radiation Control for Health and Safety Act of 1968 prevented it from being effectively carried out. Please identify those features, and any suggestions for improvement of the legislation.

NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS,
Washington, D.C., September 6, 1977.

Hon. WARREN G. MAGNUSON,
Russell Senate Office Building,
Washington, D.C.

DEAR SENATOR MAGNUSON: Replying to your letter of August 15, I give below my comments on the specific questions which you raised. In oral and written testimony I stated that the EPA had grossly overextended its interpretation of FRC responsibilities. It was stated very clearly in the Executive Order establishing the Environmental Protection Agency that matters including medical practice, patient dose limitations, shielding and medical installations, occupational exposures, etc. were to remain with the Bureau of Radiological Health which, in turn, was to remain in the DHEW. While my testimony discussed several possibilities for location of these activities, it is my strong opinion that these activities should be in the Bureau of Radiological Health in the Food and Drug Administration. The are organizationally, professionally, and temperamentally adapted to those activities, whereas in the EPA they are not only professionally unsuited but lack the support of the private sectors in all of these areas.

In the 1956 report by the Natoinal Academy of Sciences on the Biological Effects of Atomic Radiation, a recommendation was made to lower the permissible dose to radiation workers from an average of 15 rems per year to 5 rems per year. The primary scientific basis for this recommendation was the genetic effect of radiation on drosophila, a fruit fly. Subsequent studies carried out by the Russells at Oak Ridge showed that many of the conclusions drawn from the fruit fly studies were not applicable to mammals. In a subsequent report by the National Academy of Sciences in 1960, it was stated that because of the Russells' work with mice their earlier position based on data from fruit fly experiments no longer applied. (See "Biological Effects of Atomic Radiation," NAS, 1956 and 1960).

There is evidently some confusion about my oral statement relative to the linkage between radiation treatments and thyroid injury. As I understood the question which was asked of me by Senator Stevenson, my response related to levels of exposure that were considered acceptable for radiation workers. Under the normal chronic exposure conditions of 5 rems per year for radiation workers, there has been no linkage between exposure and thyroid injury that I am aware of. On the other hand, back in the '30's, the thyroid was irradiated in connection with therapeutic treatments which were then considered to be acceptable. The doses were relatively large and were acute. There is now increasing evidence that individuals irradiated at that time show an increased likelihood of developing some type of effect in the thyroid. This may or may not be of a malignant nature.

Attached is a copy of a paper which I prepared dealing with the question of radiation emitting consumer products. This is based on our official report which is now in press. The official report will be forwarded to you when available.

I am also enclosing our current list of reports as of this date; I understand that your staff has some of these. If they will indicate the ones that they do not have, we will try to supply them.

The NCRP does not of itself do any laboratory research; it depends upon the research done in many of the research laboratories all over the world. Our activities consist primarily in analyzing research done by others and evaluating its overall worth and its application to radiation protection standards. We have several committees of long standing nature that are constantly examining and evaluating the literature on the biological effects of radiation as rapidly as it appears. In addition, through our working connections, we frequently have access to research data which are not yet published.

My reference to over-reaction by the NRC to public demands for nuclear safety relates primarily to response to a few people scattered about the country who, for whatever reasons of their own, are constantly putting pressures on government agencies such as NRC, EPA, ERDA, etc. These are actions such as those by Goffman, Tamplin, Sternglass, and Cochran. Their actions are apparently designed to impede or slow down the development of nuclear power. However, because of their nature, they have impact on all other areas whether related to nuclear power or not. In general, these few people are out of step with the scientific community. They use the same data that the scientific community use, but they choose to interpret it in their own way. Actions by these people have cost the NRC, the EPA, the ERDA, the NCRP, and other organizations countless thousands of dollars and thousands of man hours of time just in responding to material which is scientifically unsound and unbalanced to begin with.

I am more than ever convinced by developments since the June 17th hearings that the Federal Radiation Council responsibilities must be taken away from the Environmental Protection Agency. In my testimony I reviewed several possible other federal agencies that might better carry on the FRC activities. I suggested two that would be more suitable than the EPA. However, my strongest feeling is that this operation cannot be carried out best at the level of *any* single federal agency. And it was for that reason that I recommended the return to something approaching the original concept of reporting to the President.

I confess it did not occur to me that this might be tied into the Executive Office through the OTP. I believe this has some very promising possibilities. It is a fact that during the original FRC operations the then current Science Advisor was brought into the discussions and was effectively the liaison between the FRC and the President. I think your suggestion here is one of great promise. If you should want to explore this further and I can be of any assistance to you, I would be more than happy to try.

The fact that OTP has a coordinating function relative to non-ionizing radiation makes even a stronger case for putting ionizing radiation in the same category.

I don't recall any testimony indicating that certain features of the Radiation Control for Health and Safety Act of 1968 prevented it from being effectively carried out. If my words appear to say that, some modification is needed. I mentioned two or three examples of how the BRH, under its mandate, may have gone too far in developing some of its standards and regulating under them. This would be a matter of interpretation and action under the Act and not a shortcoming of the Act itself. If any changes were to be made in the Act, I believe they should be changes in the direction of relaxing some of the rigidity which is in the current language. There is a great trend within the government as a whole toward excessive regulation in many areas, of which radiation is just one. Too often, because of the rigidity of the enabling legislation, the responsible agencies, through their regulations, tend to remove or reduce the possibilities for individual action and initiative which may frequently result in better or more effective means for dealing with a particular situation. Over-regulation tends to eliminate common sense and initiative. In general, I believe my feeling would be that there should be less legislation and less regulation and more opportunity for freedom of initiative and closer collaboration with the private sector.

I hope my comments above will clarify my viewpoints. I stand ready to assist your staff in any of these areas if they so desire. In the meantime, I would very much appreciate receiving a copy of the hearing record and the "Committee Print" when available.

Sincerely yours,

LAURISTON S. TAYLOR.

THE NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS,
Washington, D.C., March 30, 1977.

NEWS

THREE NEW NCRP REPORTS

The publication of three new reports was announced today by the National Council on Radiation Protection and Measurements (NCRP). The three new reports are:

NCRP Report No. 51, *Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities.*

NCRP Report No. 52 *Cesium–137 from the Environment to Man: Metabolism and Dose.*

NCRP Report No. 53, *Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women.*

The three new reports are expected to go on sale April 1, 1977.

NCRP Report No. 51 is intended to serve as a guide to good practice in radiation protection for all types of particle accelerators, taking into full consideration their broad application in research, medicine, and industry. The report presents recommendations and guidelines for many accelerator designs, performance ratings, and applications. Included in the report are recommendations concerning structural shielding and details of accelerator facility design as they pertain to radiation protection. The report is directed mainly to designers of accelerator facilities and is written from an engineering point of view. It is believed, however, that health and radological physicists, research scientist, project engineers, technical administrators, and similar specialists also will find the information provided in the report useful.

NCRP Report No. 52 resulted from an examination of all phases of cesium-137 distribution, from its entrance into the food chain to its elimination from the human body. Metabolism and subsequent dose to man from exposure to the radiation from cesium-137 are of interest principally because the radionuclide is one of the long-lived fission products which may be readily metabolized by the human body. The new report outlines the environmental deposition of cesium–137 as fallout from atmospheric nuclear testing with the intent that information could be drawn from this experience that might be helpful in assessing the relative importance of various food chain pathways. The report explores the dosimetry rather fully to give not only an average dose to the total body, but also some idea of the departures from the average that might be expected. Maximum permissible concentrations or, equivalently, maximum permissible annual intakes of cesium-137 are derived for occupational exposure to soluble compounds.

Since the NCRP issued its dose limit for fetal irradiation in 1971 (in NCRP Report No. 39), a number of reports have been published dealing with assessment of the teratogenic and carcinogenic effects of irradiation of the embryo and fetus.

Also, various governmental agencies have been concerned with the possible need to consider more restrictive radiation protection guides for potentially pregnant female radiation workers, based on the NCRP's recommended dose limit to the fetus (0.5 rem during the entire gestation period) which is lower than that for occupationally exposed persons. As a result, the NCRP determined to (1) review the basis of the current dose limit to the fetus, (2) review the recently published reports pertinent to this question, and (3) decide whether the recent information warrants any change in the numerical dose limit. NCRP Report No. 53 is the result of this study. In addition to the conclusions and recommendations, the new report includes a review of the historical background of the ICRP and NCRP dose limits and an evaluation of the status of our knowledge of teratogenic effects of embryonic and fetal irradiation, and the carcinogenic effects of prenatal irradiation. The basis for the Council's decision to make no change in the current recommendation of its dose limit to the unborn is set out fully in the new report.

Copies of the new reports can be purchased at the following prices:

NCRP Report No. 51, *Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities:*

1 through 99 copies, each copy $5.00.
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1,000 or more copies, each copy $4.50.

NCRP Report No. 52, *Cesium-137 from the Environment to Man: Metabolism and Dose:*

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100 through 999 copies, each copy $2.75.
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NCRP Report No. 53, *Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women:*

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[All prices subject to change without notice]

THE NCRP STUDY OF RADIATION EXPOSURE FROM CONSUMER PRODUCTS

(By Lauriston S. Taylor)

NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

The definition of a "consumer product" in the radiation industry is not clear. In the broadest sense it might be said that any product, device, or material that emits, or is involved in the emission of, ionizing radiation and used by a member of the public would be a consumer product. This could be drawn to include, let us say, all radiation devices used by the medical profession or the profession of industrial radiography. If it is that inclusive, it can be properly said that the NCRP's first concern with consumer products began in the early 30's because, beginning at that time, substantial attention was directed toward the improvement of apparatus and procedures to minimize at least reduce the exposure of people to ionizing radiation.

If a more narrowly defined concept is used, it might be limited to devices or materials which are used by the general public free and independent of any technical supervision or control. In old days this might have included shoe-fitting fluoroscopes or automobile-tire inspectoscopes, electrostatic or radioactive dust precipitators, luminous devices, etc. One of the first specific actions of the NCRP in this more limited area resulted from a request from the Federal Trade Commission in February 1955 asking for a statement on the safety of "over-the-counter" items containing radioactive material such as radium or polonium. A few months after a similar inquiry was made by the Isotopes Division of the AEC. Another example would be the NCRP's recommendations with regard to radiation from household television receivers in 1960. The question then might be reasonably asked as to why the Council did not more actively follow up and continue its study of radiation exposure from consumer products. To a limited extent, it did. In 1968 it established a committee on consumer products which held several meetings but failed to develop recommendations.

Part of the reason for failure was the fact that the problem was so elusive and involved such small doses that there seemed to be no working material upon which safety recommendations could be based. It is now recognized that there were some unsuspected problems of a more substantial magnitude, but at the earlier time the levels of radiation to which people were exposed were so small, and the numbers of people so small, that no basis could be found for defining protection limits. The problem is not really very different today.

In the meantime, the NCRP has established a group of committees to collect and evaluate the existing information on radiation exposure of the population from various sources. These include: (1) medical practice, (2) industrial practice, (3) production of nuclear power, (4) consumer products, (5) radiation from natural background. The report of the committees has been completed and the one on Natural Background, published.

The study by the committee on consumer products has included an evaluation of the potential exposures from some 30 product sources used by the public. The outstanding feature of this study is the conclusion, in most instances, that exposures are so small and the numbers of people involved are so few that on the average, as far as the population is concerned, the exposures must be regarded as unimportant at the present time.

At the same time there were extremely few instances where individual exposures could be regarded as having any significance. (Kindly note all these weasel words.) It may be that the problem is unimportant for the individual sources involved, but one might then properly ask, if, in the aggregate, there might be a problem. However, even in the aggregate, the numbers are so small as to defy any rational statistical evaluation of the problem. Perhaps some kind of definition to signify the presence or absence of a problem could be based on a comparison with the exposure from natural background. For example, if the levels of exposure from consumer products are less than the normal variations that the average public experiences on a day-to-day basis from variations in the levels of natural background radiation, it might be said that the extra radiation exposure is unimportant and may be neglected.

Problems on a wider scale and involving more exposure of more people appear to be arising—at least in localized regions—as a result of the use of building materials made from radioactive scrap, from building materials that are naturally more radioactive than others, from the use of byproducts (as from phosphate mining) for building materials, road pavings, etc. While levels due to such uses are higher than natural background in the area, the majority of the instances are such that the extra exposure may readily fall into a category of insignificance. Again, this is not to negate the problem, but to give some indication of its relative importance compared to the myriad of other risks with which the human population lives. Comparisons of normal risks to which the population is subjected may be interesting, and sometimes, even amusing. In any such comparison the radiation industry and the use of its byproducts must be among the safest, best understood, and most controlled industries we have to deal with. This is not to suggest relaxation of protective efforts but to urge that the problem be looked upon with care.

To illustrate the problem, some examples will be given of the average dose equivalents in millirems per year and the estimated number of individuals subjected to various types of exposure. The listing will include data from the better evaluated sources of exposure. The risk of presenting this in simplified tabular form is recognized and it should be pointed out that with each source of exposure, there will be caveats, limitations, and estimations which can only be obtained from the textual material in the report. Nevertheless, the particular numerical quantities should serve as a useful, if rough guide of the relative importance of the different sources which may be subject to some degree of control. Any of this material should be used with great caution and should not be referenced. The same numbers may or may not appear in the finished report itself. Where some obvious items of exposure may have been omitted it is because of lack of data or that the overall effects are too small.

It was suggested above that some kind of definition might be provided which would give a dividing line between radiation exposures that are psychologically worrisome and others that were psychologically non-worrisome. To provide such a base, figure 1 lists some sources that the public seems to commonly accept or about which little or nothing can be done by way of reduction or avoidance. Again the numbers in these tables are roughly rounded out.

Columns 1 and 2 give, respectively, the sources of radiation and the type of exposure for which the data are given. The latter would include for example, the whole-body dose, dose to the gonads, dose to mucous membrane, etc. The columns at the right give the product of the average dose equivalent by the estimated number of individuals exposed. These will be referred to arbitrarily as "dose index" without any further definition. It is deliberately an improper term.

It might be noted that the same product is frequently called "man-rem".* The term man in this context would be used in the generic sense, meaning "man" is a "member of the human race" or "human being", unless the context showed that only the male was meant. (c.f. Webster.)

The avoidance of the use of the man-rem concept is because the averages in column 4 could cover a fairly wide range in some instances and there might well be cases of individual exposures being unacceptably large while the average appeared to be acceptable. Furthermore, the oversimplification by using the man-rem concept has led some individuals into a dangerous interpretation of radiation effects or radiation risks.

It will be noted that the dose index resulting from television receivers and nuclear power are of the order of 1 or 2 x 10^5. The dose index from overall medical exposures is of the order 10^7 units and the genetically significant dose from diagnostic medical procedures is about 2 x 10^6 units. These might be reduced some but probably no more than a factor of 2 at this time. Natural background would produce a "dose index" of 2 x 10^7 units.

Natural background is something about which we can do very little, if anything, except to possibly change living and working habitats. For example, if an individual were to move from sea level to some point about 500 feet above sea level he would increase his annual dose equivalent by about 3.5 millirems. Even the difference between the first floor and tenth floor of an office building would involve a dose difference of 0.7 millirems per year. If half of the population of the United States were to move to a 500 foot or ten story higher altitude, the dose increase would be 3.5 x 10^5 and 0.7 x 10^5 units. These may be compared with the radiation from television receivers. Of the several exposures noted above, only those from medical procedures carry such enormous benefits that they can be justified with little question.

For these sources the requirement of unreasonable reductions could easily result in increasing the cost of medical care and forcing unwarranted restrictions on medical diagnosis, the risks of which could easily outweigh whatever the risks from radiation might be.

Figure 2 lists some of the items covered by the forthcoming report of the NCRP, following the same general scheme as in figure 1. Again, it should be emphasized that the numbers in this table have been severely rounded and no caveats or limitations are included. Comparisons between the collective effects of the doses resulting from the different sources listed becomes even more tenuous for two prinicpal reasons. First, the dose equivalents apply to a number of different individual organs or portions of the body and second, the range of dose equivalents covered in any average may be very great and hence, exclude the proper application of the man-rem concept. Nevertheless, it provides a rough picture of the relative importance of the various sources of exposure to which the general public may be sujected.

It is interesting to note that of all of the sources listed, only four would yield a "dose index" greater than 10^5 units. It will be further noted that all four of these involve exposures to limited portions of the body, as, for example, the superficial tissue or mucous membrane near the teeth or the bronchial epithelium resulting from tobacco use. The largest average dose equivalent occur for the use of radioactive material in connection with dentures or dental prosthetics. On the other hand, no evidence of injury has ever been found however high the dose may seem to be. The case for tobacco is much more complicated since there are other deleterious effects such as from tar or nicotine that may mask or add on to any radiation effects. It is not possible to singly indentify the effects of these several agents.

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*Implications of the Man-Rem Concept. Taylor, L. S. and H. O. Wyckoff. Proc. Int. Symp. on Mgmt. of Wastes from the LWR Fuel Cycle ERDA Conference 76-0701, p. 506, July 1976.

Doses from natural gas vary very widely and because the main source of exposure is from radon, the dose may diminish with longer storage time or greater transmission distances of the gas between the well and the point of use. Both cooking or unvented heating are conditions of use such that the dose may be reduced by simple means, improved venting probably being the most readily available. It is probably not practical to entirely avoid some radiation exposure from almost any gas used.

In the case of normal building materials there are again wide variations in radioactivity content which will be greatly influenced by the geographical location of the buildings and the types of building materials that are available in the area.

Wristwatches will supply a small increment to the dose and are estimated to yield a "dose index" of the order of 10^5 units. This is probably an exposure that can be substantially reduced and it is highly likely that there is only occasionally a real necessity for being able to read a watch in the darkness.

It will now be noted that the last three sources of group exposure all fall within the "dose index" range of 10^5 units and in no cases is there any evidence that any such exposures have resulted in untoward injuries.

It will now be noted that the last three sources of group exposure all fall within gories of "dose index" units. Even of these there is some possibility of further reduction, but the level of effort applied to such reductions should involve careful evaluation of the social and economic factors that would be involved.

Having listed a series of the products of the average dose equivalent by the number of individuals exposed, it is recognized that we are opening the door to temptation, i.e., the misuse of the figures for risk calculations. There will always be a few individuals who, by one process or another, will call these numbers man-rems and then convert them into some kind of "health effects."

The first step in this is to adopt, without caveat, the linear dose-effect relationship from high doses down to zero dose in the form of a single straight line. This means that there is no recovery of biological effect, there is no threshold of effect and all dose effects are totally additive no matter how and when the dose is received. Under most circumstances this has to be nonsense but it will, nevertheless, be used to enter upon what I have referred to as the body counting game.

During the last war we counted enemy planes that we had "shot down" even though by the middle of the war we had shot down twice as many as had ever been produced; we count bodies of the enemy and those of our own men when we ar trying to explain a war as in Viet Nam or we count the bodies of the policemen and the bodies of the demonstrators when we try to prove who was right or wrong in some protest. By the simplistic use of the linear dose effect relationship and the man-rem concept, it can be said that any one exposed to 1000 rads will die, regardless of how the dose is delivered. There are other methods for calculating bodies that appear to be much more sophisticated but that are in fact, no better. The problem is further complicated when attempts are made to establish a theoretical relationship between health effects and deaths.

As a forewarning about the misuse of the data in this report, it should be emphasized that the three largest exposures in the report are partial body and there is no way of equating them to whole-body doses, gonad doses, or whatnot. In spite of the probable misuse of this data, it was nevertheless, considered worthwhile to present it in the fashion given here. Limited comparisons will be valid and the final results may be of some assistance in deciding to undertake specific studies in the field of regulation or control of radiation in consumer products.

In conclusion, the NCRP is stepping up its concern with radiation exposure resulting from consumer products and at this time I would not venture to suggest what its ultimate position may be. It recognizes that, at some stage, the problem has to be treated in some pseudo-quantitative fashion. However, at the present time, the Council is not enthusiastic about the attempts to legislate or regulate levels of safety into many radiation uses which are based on such shaky models and assumptions as to provide readily distortable conclusions. The Council is seriously examining the matters of radiation risk on a quantitative basis, but not with the over-simplified models that have been appled in recent years. It is fairly certain that, over the next few years, the NCRP will include such detailed studies as it considers rational in relationshp to consumer products, even though the end result for many of these products may result in the expression of the opinion that they are unimportant.

The main benefit of this study has been in pointing out what may be a way to avoid future problems rather than indicating any serious problems at the present time.

FIG. 1

Source	Type of exposure*	Number exposed	Average dose equivalent (mrem per year)	Dose index (exposed groups) ×10⁸	×10⁷	×10⁶	×10⁵	×10⁴	×10³	×1
Television receivers	GD	10^8	1.0				1			
Nuclear power	WB	2×10^8	1.0				2			
Medical	WB	10^8	100.0		1					
	GSD	10^8	20.0			2				
Natural background	WB	2×10^8	100.0		2					
10 story building**	WB	----------	.7				0.7			
500 ft. altitude**	WB	----------	3.5				3.5			

*Type of exposure (dose equivalent): WB, whole body; GD, gonads; GSD, genetically significant dose.

**Increase in natural background radiation.

FIG. 2

Source	Type of exposure*	Number exposed	Average dose equivalent (mrem per year)	Dose index (exposed groups) ×10⁸	×10⁷	×10⁶	×10⁵	×10⁴	×10³	×1
Uranium in dentures	A	9.0×10^7	7.0×10^4	65.0						
Dental prosthetics	B	10^7	6.5×10^4	6.5						
Tobacco	C	5.0×10^7	8.0×10^3	4.0						
Natural gas:										
Cooking	C	1.3×10^9	9.0			1				
Unvented heating	C	1.6×10^7	22.0				3			
Building materials	WB	10^8	7.0				7			
Television receivers	GD	10^8	1.0				1			
Wrist watches:										
Ra-226	GD	10^9	3.0				1			
H-3	WB	1.6×10^7	.6					1		
Pocket watches	GD	2.0×10^4	6.0							120
Clocks	WB	10^7	3.0					3		
Highway materials	WB	5.0×10^6	4.0					2		
Smoke detectors	WB	4.0×10^6	1.0						4.0	
Electron microscopes	WB	10^4	500.0						3.0	
High voltage switches	GD	4.0×10^4	30.0						1.2	
Air transport:										
Passengers	WB	6.0×10^6	.5						3.0	
Crew	WB	2.0×10^4	5.0							100
Gas discharge tubes	WB	5.0×10^5	1.0							500
Airport passenger inspection	WB	10^7	2.0×10^{-3}							200
Thorium in dosimeters	WB	1.5×10^5	10^{-3}							200
										0.1

*Type of exposure (dose equivalent): A, superficial tissue; B, mucous membrane; C, bronchial epithelium; WB, whole body; GD, gonads.

Senator Stevenson. Our next witness is Dr. Irwin D. J. Bross, director of biostatistics at the Roswell Park Memorial Institute.

Dr. Bross, you are welcome to summarize your testimony. If so, I would be happy to put the full statement in the record.

STATEMENT OF IRWIN D. J. BROSS, DIRECTOR OF BIOSTATISTICS, ROSWELL PARK MEMORIAL INSTITUTE

Dr. Bross. Mr. Chairman, I believe that my statement is important enough to give in full.

Senator Stevenson. All right.

Dr. Bross. Mr. Chairman, I appreciate this opportunity to testify before your committee because I believe it could result in protecting the American public against the hazards of unnecessary diagnostic radiation 3 to 5 years sooner than what might otherwise be the case.

In the past year there has been a major scientific breakthrough in our knowledge of the health hazards of ionizing radiation in the 1 rad range. I am talking about the range between 100 millirads and 10 rads where most of the current exposures to medical or nuclear radiation now occur. For the past 20 years or more there has been a guessing game going on concerning the health hazards at the 1 rad level. Up to last year all the estimates of hazard were based on extrapolation—which is often a technical way of saying guesswork. The BEIR report uses mainly linear extrapolation from very high dosage levels to low dosage levels. In other words, if you estimate a health effect at a 1,000 rads, then you say there will be one one-thousandths of this effect at 1 rad. This is a reasonable thing to do if you don't have anything better. Nevertheless, it has been bitterly attacked as a gross exaggeration of the actual hazards by the defenders of radiation technologies. Even today, radiologists tell the press that 1 rad is virtually harmless. There has also been extrapolation from rodents to man, and this usually involves extrapolation from high dose to low dose as well. This is guessing about guesses, but on this flimsy basis radiation biologists and health physicists have also claimed that the low doses are virtually harmless.

There was some solid information 1 year ago that the 1-rad level was far from harmless, but this evidence was ignored or concealed by the guessing games and controversy that had gone on for so many years. In the past year there has been a drastic change in this situation. First, let me give you the good news, then the bad news.

The good news is that the guessing game is over. My team at the biostatistics department at Roswell Park Memorial Institute for Cancer Research in Buffalo, N.Y., and the research team of Mancuso, Stewart, and Kneale have independently applied new technology to some old data to obtain the first clear-cut assessment of health hazards at the 1-rad level on the basis of data on human beings who were actually exposed to radiation at this level. The two studies have entirely different data and methods. One involves the nuclear radiation to workers at the Hanford Reprocessing Plant, and the other involves diagnostic radiation. The results mutually confirm each other in general, although there are some specific differences. So we no longer have to guess at what is happening; we now have rather precise estimates.

The bad news is that these new findings indicate that the hazards at 1 rad are far worse than anyone expected. They are much worse than the extrapolative estimates from the BEIR report. These two independent studies clearly show that the claim that these low levels are harmless is complete nonsense—and very serious nonsense at that.

These major scientific achievements in the past year might seem to deserve a Nobel Prize, but, in point of fact, in both cases the reward was a cutoff in the funding of the research by angry radiation technologists at ERDA and angry radiologists at the National Cancer Institute.

Millions of Americans have been exposed to diagnostic X-ray which have sometimes done serious harm, but we cannot do much about this now except to wait a few years and hope to catch the leukemia or cancer early. Millions of more Americans will be exposed to unnecessary X-ray next year and years after that, and there is something that can be done, and done promptly, about this. What Congress can do—or what might even be possible under Executive order—is to stop paying for the millions of unnecessary X-rays that are currently being given to the American public each year. These X-rays are ordered routinely because they will be paid for by third-party insurers just as routinely. If they weren't paid for, they would not be given.

On the basis of the data that I received from the National Center for Health Statistics—NCHS—for the 1974 survey of the general practice of medicine, I would conservatively estimate that 10 million Americans get an unnecessary X-ray exposure each year. There are about 15 million who get an X-ray. About half a million get X-rays for very serious conditions where, say, the X-ray might save their lives. This amounts to only 1 patient in 30. On the other hand, about 11 million are getting X-rays for conditions which are classed as not very serious, or where there is no known medical problem. This amounts to about three-quarters of the X-rays. Many—I think most—of the X-rays are unnecessary.

In a survey reported by the American Medical Association, it is estimated that three out of four American physicians practice what is called defensive medicine. This means that three out of four physicians are ordering unnecessary laboratory tests or X-rays or both. The tests are for the protection of the doctor in the event of a malpractice suit. Although doctors hate to have a nonphysician point this out, let me point out that this is a clear violation of the Hippocratic Oath. Every doctor has sworn not to give any treatment that will benefit the doctor and harm the patient.

A radiologist may have the opinion that diagnostic X-rays are harmless. All this means is that they are at least 10 years behind the times in their knowledge of radiation hazards. For at least 10 years there has been no scientific question that they involve some degree of risk, and this is clear in the original BEIR report which was written around 1970. In this situation, a radiologist's opinion is worthless because it is flatly contrary to well-established scientific facts. There is no question that there is a hazard, although there can be some debate about the new numerical estimates. The Nuclear Regulatory Commission is currently setting up, at my request, a public debate on our new finding in an "adversary science" format.

In addition to the practice of defensive medicine, there are many other reasons why unnecessary X-rays are given. These include sheer habit, the persistence of antiquated notions about annual examinations for tuberculosis and other diseases, and the inability of patients to get possession of their own X-rays when they change doctors.

At the root of the trouble, as usual, is money. The real reason that these unnecessary X-rays are given is because someone will pay for them, and that someone is usually a third-party insurer. The failure of third-party insurers to monitor the need for quality of medical services is the source of this and many other medical abuses in our medical system. It is the reason why patients get so many dangerous services and probably pay as much as $30 billion or $40 billion in unnecessary medicaid, medicare, or other third-party costs.

Ten million X-rays is a ballpark estimate for the unnecessary X-rays delivered each year, and it is probably much too low. But it is very hard to get accurate estimates. This is the best I could do.

The figures I cite do not include X-rays delivered to hospitalized patients, dental X-rays, or special X-rays. It probably misses many of the routine chest X-rays or other X-ray exposures that are required as a condition for employment. If we take $30 as a conservative ballpark estimate for the cost of an X-ray, then we are talking about more than one-third of a billion dollars that taxpayers can save right away if we stop these unnecessary X-rays.

I am not a lawyer, and I do not know all the complexities. However, I think we can stop these unnecessary X-rays almost overnight if Congress or the executive is willing to risk the fury of the radiologists whose income comes from these X-rays.

There are two things we need to do. First, a certificate of necessity signed by two physicians should be required before there can be any third-party payment for X-ray. This certificate of necessity can have only minimal information such as age, sex, diagnosis, and identification of patient. I would like to see a patient's signature indicating there had been informed consent to the X-ray, but this might be asking too much.

The second requirement is that these certificates of necessity be monitored. This is absolutely essential. In other words, they should be centralized and put into a computer. There is no need for an elaborate computer system—the information can be typed verbatim into a terminal. What is essential is that there be careful surveillance. As an expert on monitoring systems, I will simply note that it is entirely unnecessary to rely on medical opinion in the monitoring. It is relatively easy to pick out persons who are issuing false certificates by analysis of patterns of X-ray usage in the data. Naturally, the doctors should have a hearing and appeal procedure in a quasi-judicial process. If there is sufficient evidence of falsification, the doctor's signature would not be acceptable on a certificate of necessity for a given number of years, as a penalty.

I will not go into details of how this monitoring system would work. I would simply say that it would be possible to run it for a few million dollars a year. While it would not get every person who issued a false certificate, it would screen out the worst offenders. It would save, I believe, at least 10 times its costs.

The third-party insurers may not be happy to have this arrangement because they have seen their role as a conduit for cash flow from the patient to the physician. They try to avoid responsibility for monitoring services, and this is what the physicians want. However, unmonitored third-party payments have resulted in a serious deterioration of the quality of care in this country. It is not just unnecessary X-rays, but unnecessary drugs, surgery, hospitalizations, and other medical services. It makes no sense to extend the coverage of third-party insurance without taking effective steps to control both the quality and the costs of medical care. These can best be controlled simultaneously. If payment were made only for services that were necessary, safe, and effective, the present costs could be cut by at least 25 percent, and probably 50 percent.

While the requirement for a "certificate of necessity" is seemingly a simple, reasonable step to end the serious current abuses of medical radiation technology, it was bitterly opposed by radiologists when I made the suggestion in conjunction with a report of our findings on radiation hazards. The radiologists' anger here reflects the basic issue: They are not going to let anyone who is not a physician tell them how to practice medicine. This is in many ways the heart of the whole matter. The professionals for many years have been in control of the decisionmaking processes affecting their profession. I am not talking only about doctors. This is true for scientists, technologists, and many other professionals. The evidence is overwhelming that when the decisions are made by professionals they are made in the professional interest and not in the public interest whenever it is a conflict between the two. The strategic mistake here is to let technologists have the say about the uses of their technology. This has been a major mistake that Congress has made for the past 20 years. As a result, the public has lost control of the professionals who are supposed to serve them. When professionals run things to suit themselves, they often serve the public very badly.

What I am proposing is a small step, a first step, for reassertion of control by the public of technology. In the last 20 years, technology has often been used in such a mindless way—such as in the millions of unnecessary X-rays now being delivered—as to be a threat to the public health and welfare.

I am not a politician, but I believe that the public is sick and tired of being the target for the many abuses of technology that have occurred in the past decade. They are tired of being subjected to radiation merely to protect their doctor from a lawsuit. They are disillusioned with nuclear physicists who produce 600,000 gallons of high-level wastes at West Valley and then admit they have no idea how to dispose of it safely. They are tired of having extremely dangerous chemicals dumped into the water supplies whenever someone wants to make a fast buck. They are fed up with so-called scientists who are willing to create a whole new kind of dangerous biological contaminant merely to get their share in the next "big science" raid on the Federal Treasury—in the name of "recombinant DNA research" or "genetic manipulation."

We do not need repair of a few more damaged genes in 2077, we need to stop the whole degradation of the human genetic material by X-ray exposures which are occurring in 1977. In sum, I think the public is fed up with professionals who are supposed to serve them but instead who bully, abuse, swindle, harm, or otherwise mistreat a helpless public.

The Federal agencies with some responsibility for radiation, the Bureau of Radiological Health, the National Cancer Institute, the Energy Resources and Development Agency, the Nuclear Regulatory Commission, and others, have been passing the buck on protecting the public against radiation hazards for many years. The same is true for protecting the workers in nuclear or other radiation exposed industries against the hazards. I think it is time that Congress took positive action to protect the public, even if it means some flak from the medical profession or the nuclear industry. I believe it is up to the President and it is up to Congress to send the professionals in this country a message, and I believe this is the way that Congress can have some input into this research. You have to send them a message. It has to be sent in the one language that all professionals can understand, irrespective of their technical jargon: When there has been particularly bad service, as in ERDA or the NCI or NASA or NAS, there should be a drastic budget cut, say 25 to 50 percent, to let the professionals know that they had better start acting in the public interest if they want stay in business at all.

Since I find that I have a few more minutes than I expected, let me say a little more about why the hazards of diagnostic radiation are so much worse than anyone had expected. On Tuesday of this week I testified with three other experts before the Fountain Committee on Oversight of the "Conquest of Cancer" program of the National Cancer Institute. There were the customary statements about the need to find the cause of cancer. I find this annoying because the cause of cancer was well-known to every competent scientist working on carcinogenesis before the conquest of cancer program began—and even earlier.

So let me make the belated public announcement that we know the cause of human cancer—all cancers—and have known this for at least 5 years. The cause of cancer—the first event in the chain of events that leads to human cancer—is a biochemical lesion or breakpoint in the delicate structure of the DNA in human genetic material. This is how all human cancers start, although there are some different chains of events that come later and determine whether the individual gets leukemia in 7 or 8 years, breast cancer or lung cancer in 15 to 20 years, or whether the leukemia or other disease show up in the child of the person exposed.

The first event—the cause of cancer—is too small to detect directly and the damage must be magnified many millions of times before it can be seen. The DNA structure itself contains the information necessary to make a viable human being and keep this human being alive. Each section of this complicated chemical molecule contains instructions for doing something or making something such as an enzyme. When there is a breakpoint in the DNA, this puts misinformation into the instructions. Depending on where the breakpoint occurs the damage may be drastic enough to prevent the cell from reproducing, or it may be slight enough to result, say, in the loss of a single enzyme.

There are two main semantic problems with the word "cause" here. The first is that the "effect," cancer, takes so long to occur—15 years for breast cancer. The other is that there can be more than one "effect"—the same break that may result in leukemia may also result in allergy or susceptibility to pneumonia and other diseases. We know very exactly about the long delay because of accidental human experiments that occur when X-rays are used in a foolish way. There is at present an epidemic of breast cancer going on in Rochester, N.Y., produced by giving 200 rads to young women with postpartum mastitis, a painful but transient infectious disease. Among 600 women given this treatment by radiologists, some 30 got breast cancer from the X-ray. They got this cancer starting about 15 years from the time they got the X-ray—both times being accurately known in this instance.

Similarly, we know about the latent period for thyroid cancer, because, as the recent NCI pamphlet warning persons receiving head and neck X-ray to come in for examination explains, there have been at least five separate thyroid cancer epidemics produced by radiologists in the treatment of very minor diseases—acne, pinworm, ——, ——, and enlargement of the thymus in babies. The latter is not even a disease, but a condition which corrects itself in a few weeks. A more complete catalog of radiological horrors appears in the March 1977 report on mammography just issued by the NCI. The warning should have advised examination for breast cancer and lung cancer because these may also have been produced by the mindless use of X-ray in these five diseases and there are other uses not listed here.

I might say that I spent a good part of last Wednesday in Washington trying to find out what, if any, agency of the Federal Government had the power to step in and stop these epidemics of cancer from this unnecessary X-ray use, but I was unable to find any agency with this authority. I think emergency legislation is needed to correct this.

From these repeated epidemics of iatiogenic cancer, we can learn quite a lot about the chain of events between the invisible breakpoint in the DNA at the time of the X-ray and the occurrence of cancer many years later.

We don't know all the details but we do know the general process. The reason it takes so long is that there must be a magnification of the damage by the cell doubling and redoubling and so on and on, until there have been 30 or more doublings of the cell population and billions of daughter cells. The doubling time is often 6 months or more at the start. Since 30 doubling times are needed and it takes about half a year to double the population, there is a 15-year latent period before the breast cancer starts to appear. The Rochester breast cancer was produced by radiologists between 1940 and 1960 and is just showing up.

In the 30 doubling times there is a process going on which, to the annoyance of all my friends in biology. I call a "di-evolutionary" process. In others a normal cell under the close control of similar cells—a specialized cell—reverts to a free-living cell that can migrate in the blood stream and eventually grow anywhere in the body. This is what is called "cancer" and this is how X-ray causes cancer.

One final point. I said that the risks at 1 rad are far worse than anyone had thought and now, perhaps, you can see why. Radiologists believe in the myth that the risks go away when the dosage is "fractionated"—that is, given in a series of smaller dosage. The grim truth is that fractionated dosage are far more efficient in producing cancer than high dosage. With low dosage each shot may count, but with high dosage, there is so much damage to the DNA that the cell dies and the cancer is cured. This is why extrapolating from the inefficient cancer-producing effect at high doses to the efficient effect at low doses greatly underestimates the actual danger.

Thank you.

Senator STEVENSON. You say that this level of exposure is far worse than anybody had expected. How much worse?

Dr. BROSS. They are orders of magnitude worse. Can I give you a quick explanation of why this occurs?

Senator STEVENSON. Yes. Go ahead.

Dr. BROSS. I think if I tell you what's going on you can understand it. The damage that is produced by X-ray is to break into the delicate structure of human DNA, to make a breakpoint in that structure. This produces all cancer. There is no question. There has been no question for 10 years as to what causes cancer, at least the first event that leads to cancer. That's it.

It takes a long time to appear; 8 years for leukemia, 15 years for solid cancers, because you have to increase the cell population to many millions to billions, at least 30 doubling times. You have to increase the cell population by this, which takes 6-months at a crack to double in order for this to appear as a visible cancer.

Now, the reason why high levels of radiation are very inefficient at producing cancer is that you cause and cure the cancer at the same time. You have this delicate structure, and you produce one more break in it. You may only produce a break that will allow the cell to reproduce and go through all of this doubling, compete with normal cells, and eventually become cancerous.

On the other hand, if you produce heavier damage in the cell, what you do is block the reproduction or stop the process at some intermediate point. Therefore, when you use dosages very lightly, then you produce cancer very efficiently. That's at these low doses. When you use doses very heavily, then you essentially frustrate your effort to produce cancer, in a sense, if that was your effort.

And that is, in fact, how you treat cancer. That is how this works against cancer, because when you treat cancer with radiation you give very high doses. You produce so much damage that the cell reproduction is completely blocked. And this is going to be how the cells are killed.

So, in other words, when we get into these high levels, you are doing things very inefficiently, in that sense. And that is why when we extrapolate data from the radiation given at high levels to the radiation given at low levels on a per-rad basis, you can get much more cancer than you would expect from linear extrapolation.

Does that explain this at all?

Senator STEVENSON. I am making progress slowly. But you single out 1 rad. You say it is worse than anyone expected at that level. We are not going to prohibit all X-rays. There are going to be X-rays. And it seems to me that there has to be at some point some determination as to what is an acceptable level. Is 1 rad acceptable or unacceptable?

Dr. Bross. Let me just explain this. The 1 rad refers to a range up or down by a factor of 10; so I am talking about a range, OK. It is in this range that most diagnostic radiation is given. It is in this range that the nuclear exposures at Hanford and other reprocessing plants mainly occur.

Now, the question on this is, "What are you getting for this exposure?" We now know that this is not harmless. So there is a cost. There is a serious cost. You now have to ask, "What are you getting for this cost? What is the benefit?" And you now have to weigh this.

What I am saying is that, for example, if the persons have a skull fracture and there is a real urgent situation which is life-threatening, and you have this situation, then your benefits outweigh the risk. This applies even with mammography. If a woman comes in with a lump in her breast, and she is not certain of cancer, maybe only 1 of these in 10 will be a case of actual cancer. However, her chances of having cancer are so high that you would be willing to, or she would be willing to, or she should have the option— informed consent—to make the decision to get an X-ray. And here, in this case, it is to her benefit to have a mammography in order to make the diagnosis. But if she is a perfectly healthy woman, as far as it is known, it is just exactly the opposite. There is very, very little benefit. And now there is this serious hazard. So you do not say 1 rad is harmless.

Senator Stevenson. Can you tell me what the current average exposure of the American public is to ionizing radiation from medical and dental X-rays?

Dr. Bross. I am sorry, I cannot. I do not have that figure.

Senator Stevenson. Now, you said that funding, your funding was cut off by angry radiation technologists at ERDA.

Dr. Bross. No. At NCI. Both of these programs had their funding cut off. Mancuso was supported by ERDA. And ERDA cut his funding. And right in the middle of some very important findings, too.

Our funding is from National Cancer Institute, on a program which I was renewing, which I had for 9 years. And that is a different source of support.

Senator Stevenson. Those are serious allegations against those two agencies. Can you amplify your comments?

Dr. Bross. Senator, I would be glad to do that at length, but I do not feel my personal problem should interfere with my other testimony, because I am here to testify on behalf of the public health, and not my own interest. And so I would be glad to talk about that to anyone who would talk to me. But if I would——

Senator Stevenson. But these are serious allegations against those two agencies, and they ought to be substantiated.

Dr. Bross. I believe I could present you with the factual information on this to substantiate both of the charges, both for ERDA and for NCI.

Senator Stevenson. All right. I would like to follow up on that account, and also with some additional questions in writing. We are running out of time now.

Dr. Bross. Yes.

Senator Stevenson. Will you submit the reports from those two studies to us for the record?

Dr. BROSS. Yes; I will do that.

I wonder if I could just submit one document, in view of your questioning. This is put out by the National Cancer Institute. It is entitled, "Did You as a Child or Young Adult Have X-Ray Treatment Involving Your Head and Neck?"

This was a report of five separate epidemics of cancer produced by treatments of the following conditions, according to this: the ringworm of the scalp, enlargement of the thyroid gland, deafness due to lymphoid tissue, enlargement of the tonsils, and acne. And these were given at dosage levels that were previously mentioned as being essentially harmless. They are not high treatment levels.

Senator STEVENSON. Let me interrupt at this point. I think you misunderstood Dr. Taylor. I do not think he was suggesting that no one had ever been injured by exposure to radioactivity. He said that no one had been injured by exposure to radioactivity at permissible levels. And he was talking about an occupational environment.

Dr. BROSS. The levels he mentioned, not the current permissible levels, were 30-rad levels, levels in that general area, that we are talking about here.

Now, some of these are higher. They are not the heavy doses which are given for cancer, like 6,000 rads. These are mild doses, in the range he was talking about. The current level is 5 rads per year for a nuclear worker in an installation. And that is why I am going to NRC, to try to get them to cut that by a factor of 10.

Senator STEVENSON. Well, having just had part of my thyroid gland removed, I am not unfamiliar with some of the risks of exposure to radiation. I am still recovering from that surgery.

Thank you very much, Dr. Bross.

We will be following up, as I indicated earlier.

Dr. BROSS. Thank you, Senator.

[The following information was subsequently received for the record:]

ROSWELL PARK MEMORIAL INSTITUTE,
Buffalo, N.Y., July 7, 1977.

SENATOR ADLAI STEVENSON,
United States Senate,
Committee on Commerce, Science, and Transportation,
Washington, D.C.

DEAR SENATOR STEVENSON: As promised at your hearing on June 17, 1977, I have prepared a substantiation of the charge that I made at this hearing. This material is enclosed together with the attached exhibits.[1]

The issue here is of long-term public importance even though there is little short-term prospect of reversing the ERDA or NCI actions. It is an example of an evil which has steadily grown over the past 20 years as "Big Science" federal agencies have taken over support of scientific and medical research. These agencies have used the peer review machinery to reward scientists whose findings agree with agency policies and to punish those whose findings are going to "rock the boat". Unfortunately it is impossible to protect the public against hazards from the misuse of technology without rocking the boat.

The effects on American scientists are abhorrent. Many are now unwilling to report their findings in an intelligible way if there is any chance that some influential group will object. Many work on "safe" technical trivialities and avoid "dangerous" topics which could benefit the public health and welfare. Publication in scientific journals is increasingly dominated by the "Big Science" agencies (which can, for instance, have entire issues of Science to promote their programs). It is very unhealthly for the general public and for genuine scientific research.

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[1] The exhibits have been placed in the committee files.

Very sincerely yours,

IRWIN D. J. BROSS, PH. D.,
Director of Biostatistics.

Enclosure.

A REPORT ON THE ACTION OF TWO FEDERAL AGENCIES, ERDA AND NCI, IN TERMINATING FUNDING FOR TWO MAJOR STUDIES OF THE HEALTH HAZARDS PRODUCED BY LOW LEVELS OF IONIZNG RADIATION

A RESPONSE TO A QUESTION RAISED BY SENATOR ADLAI STEVENSON III, DURING THE TESTIMONY OF DOCTOR IRWIN BROSS AT A HEARING OF THE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION ON JUNE 17, 1977

INTRODUCTION

At the June 17 hearing of the Committee on Commerce, Science and Transportation chaired by Senator Adlai Stevenson III, Dr. Irwin Bross made the following statement in the course of testimony on major new findings in radiation hazards in the "one rad range" (100 millirads to 10 rads):

"These major scientific achievements in the past year might seem to deserve a Nobel Prize, but, in point of fact, in both cases the reward was a cutoff in the funding of the research by angry radiation technologists at ERDA and angry radiologists at NCI."

The matter came up in cross-examination as follows:

"Senator STEVENSON. Now, you said that funding, your funding, was cut off by angry radiation technologists at ERDA.

Dr. BROSS. No. At NCI. Both of these programs had their funding cut off. Mancuso was supported by ERDA, and ERDA cut his funding. And right in the middle of some very important findings, too.

Our funding is from National Cancer Institute, on a program which I was renewing, which I had for nine years. And that is a different source of support.

Senator STEVENSON. Those are serious allegations against these two agencies. Can you amplify your comments?

Dr. BROSS. Senator, I would be glad to do that at length, but I do not feel my personal problems should interfere with my other testimony, because I am here to testify on behalf of the public health, and not my own interest. And so I would be glad to talk about that to anyone who would talk to me. But if I would . . .

Senator STEVENSON. But these are serious allegations against those two agencies. In terms of them, they ought to be substantiated. We do not have to go into it now.

Dr. BROSS. I believe I could present you with the factual information on this to substantiate both of the charges, both for ERDA and for NCI.

Senator STEVENSON. All right. I would like to follow up on that account, and also with some additional questions in writing. We are running out of time now."

The following statement was prepared in response to Senator Stevenson's request. Insofar as possible, it is restricted to statements for which there is documentary evidence, where factual backup is available even if it is not cited, or where there is an eye-witness testimony (concerning the site visit). Because of this restriction, this response will deal more fully with the NCI peer review process than the ERDA review. Dr. Bross attempted to obtain documentary evidence for the Mancuso decision from ERDA under the Freedom of Information Act but with limited success.

MATTERS OF RECORD

While the original statement in the June 17 testimony is correct as it stands, it is a somewhat informal way of making a serious charge against two federal agencies, ERDA and NCI. Therefore a more formal restatement of the charges seems appropriate. Since there are components of the original statement which are matters of record, these will be dealt with first so that the restatement of the charge can be as brief as possible.

It is a matter of record that the requests of the principal investigators of the two research teams that were carrying out these studies on the hazards of low levels of ionizing radiation for funds to continue this research were disapproved. ERDA has already cut off the Mancuso funding and the NCI has disapproved renewal of the Bross program in September 1978. Again, it is a matter of record that the scientific findings of both studies, independent but mutually collaborative, indicate that the health hazards in the one rad range, determined from data on humans actually exposed to this level of nuclear or diagnostic radiation, are far more serious than had previously been estimated. They are orders of magnitude worse than the estimates by linear extrapolation from high dosage levels presented in the BEIR report,[1] long the basis for regulatory policy.

It is again a matter of record that the disapproval of both funding requests involved use of the machinery of what is called "peer review." The procedures used by ERDA differ in detail from those used by the NCI, but the essential characteristics of the peer review process is the same in both cases. The decisionmaking involves a small number of professionals chosen by the agency. Decisions are made in secret and reporting of the results is anonymous. There is no appeal under ordinary circumstances. The decisionmakers have no accountability to the public but are accountable to the agency in the sense that their reports go to the agency. The closed character of the peer review process reflects the philosophy that decisions on professional matters should be made by professionals and the public should be excluded. With minor variations similar procedures are used in decisionmaking by all of the "Big Science" federal agencies that have multimillion-dollar budgets. The crux of the issue here is the way in which the peer review machinery was used in the decisions to cut off funds.

Finally it is a matter of record that the peer review process in each instance was primarily focused on a specific scientific report. The ERDA decision concerned the study of deaths among the workers at the Hanford Reprocessing plant by Mancuso, Stewart and Kneale. This material will shortly appear in Health Physics (Exhibit 1). The NCI decision was somewhat broader, but again the focus was on the study of genetic damage from diagnostic X-ray by Bross and Natarajan that appeared in the Journal of the American Medical Association on May 30, 1977 (Exhibit 2). The somewhat unusual circumstances that make the materials at issue readily available to the public also serve to open the closed peer review process to more critical examination than would ordinarily be possible.

RESTATEMENT OF CHARGE

In the original informal statement the charge was that for both the Mancuso and Bross research programs (identified more fully in the previous section) there was a "cutoff in the funding of the research by angry radiation technologists at ERDA and angry radiologists at NCI."

This charge can be stated somewhat more fully and formally (using the matters of record given in the previous section) by making the following five points, each of which will be detailed subsequently:

(1) Both federal agencies have policies, programs and professional personnel involving radiation technology, in-house and grantees, and a strong motive to block or suppress further research on the hazards of low-level ionizing radiation.

(2) Both federal agencies had the means to stop further research by using the easily manipulated peer review process as an instrument for cutting off further funding for the two programs.

(3) Both federal agencies used the peer review process to produce the desired verdict, primarily by selection of persons and panels whose professional interests were threatened by the scientific findings. ERDA used in-house reviewers and NCI used radiologists and other professionals despite the clear conflict-of-interest involved.

(4) The manipulation by both agencies precluded any objective scientific review of the two research programs. The review was not carried out by the scientific "peers" of the investigators. The NCI site visit was disrupted by an angry radiologist. The resultant NCI "critique" supporting the verdict was little more than selected adversive statements, scientifically irrelevant "putdowns" of the program.

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[1] BEIR report: The Effect on Population of Exposures to Low Levels of Ionizing Radiation. National Academy of Science, 1972.

(5) As a result of the actions of the two federal agencies the American public has been deprived of research of vital importance to the public health and public policy (particularly energy policy), freedom of inquiry by American scientists has been restricted, and the integrity and credibility of the medical and scientific community has been eroded by this abuse of the peer review machinery.

SUBSTANTIATION OF POINT 1

This section deals with the point that "Both federal agencies have policies, programs, and professional personnel involving radiation technology, in house and grantees, and a strong motive to block or suppress further research on the hazards of low-level ionizing radiation".

The long-standing and close connections of ERDA, its sister agency (NRC) and their common predecessor agency (AEC) with the nuclear industry is too well known to require documentation here. That ERDA has policies, programs and professional personnel that are directly connected with radiation technology, both in ERDA and in institutions or corporations funded by ERDA again seems a matter of common knowledge.

The findings of the Mancuso, Stewart and Kneale research (Exhibit 1) are clearly a threat to the multi-billion nuclear industry. For example, the excess deaths from leukemia and lung cancer occurred for exposures of Hanford workers at dosage levels that were nearly always within the 5 rad level permitted by the AEC and currently by the NRC. Dr. Bross plans to present his findings (Exhibit 2) on health hazards in the one rad range at a special hearing this Fall as part of an effort to obtain reduction by a factor of 10 in permissible levels by the NRC. Operations at much stricter levels would add to nuclear industry costs and might even result in the prohibition of certain nuclear processes, particularly some of the more hazardous reprocessing operations. The resistance of the nuclear industry, ERDA, and the NRC to this tightening of permissible levels is also common knowledge.

Apart from the general threat from the Mancuso, Stewart and Kneale findings, there is a specific threat to ERDA and its contractors. The nuclear industry has long insisted that no one has ever died from exposures occurring in the regular nuclear operations (exclusive of major accidents) but the Mancuso findings show that leukemia, lung cancer, breast cancer and other malignant diseases are produced by the exposures that occur in regular operations. There are, therefore, well-documented deaths that have occurred and this may lead to lawsuits by exposed nuclear workers against federal agencies, such as ERDA, and companies that were contractors for ERDA or AEC. Such threats provide ERDA with a strong motive to block further research by the Mancuso, Stewart and Kneale team.

Documentary evidence in support of the contention that ERDA and its allies with a large stake in nuclear technology have a strong motive to suppress research is provided by the efforts to block publication of these findings. Exhibit 3 (correspondence with Dr. Karl Morgan) begins with a letter from Dr. Karl Morgan to Dr. Irwin Bross, asking him to review two seemingly contradictory papers and to explain the reason for the contradictions. The letter states "Now NRC is determined to suppress publication of the latter paper". This refers specifically to an earlier draft of the Mancuso, Stewart and Kneale paper that is Exhibit 1.

The Morgan letter indicates that efforts to suppress a previous paper by Milham were successful and suggests a historic pattern of suppression of information on low levels of ionizing radiation. Although it would be too large a task to document this history here, it might be noted that the action against Mancuso by ERDA is the latest in a long series of similar actions going back about 25 years. At that time, the AEC was determined to suppress the information about the hazards of fallout (again, a hazard from low levels of ionizing radiation) which threatened the nuclear weapons testing programs (then conducted above ground). The AEC embarked on a continuing policy of retaliating against scientists who publicly discussed these radiation hazards. Anyone interested in establishing this pattern of suppression and repression by the AEC should take testimony from Drs. Gofman, Tamplin, Morgan, Sternglass and others who were the predecessors of Mancuso.

Let us now turn to the policies, programs, and professional personnel of the NCI that are directly involved with radiation technology. These are not as well known as those of ERDA. Nevertheless the NCI commitments to medical radiation technology are substantial. Of special relevance here are NCI programs involving radiation surveillance of asymptomatic populations. The largest and best known of these is the controversial Breast Cancer Detection Demonstration Programs (BCDDP) in which a guideline against screening women under 50 was issued in August 1976 because the radiation hazards far outweighed the benefits in this group of women. Dr. Bross played a public role in forcing the NCI to stop rescreening of the women, a role that did not endear him to the radiologists. The attitude of the radiologists is indicated by the fact that they ignored the NCI guideline while continuing to accept NCI funds (although it is against federal laws to fund NCI programs which are not in compliance with guidelines). Documentation concerning the BCDDP and its radiologists has been submitted in conjunction with testimony by Dr. Bross before the Intergovernmental Relations and Human Resources Subcommittee of the Committee on Government Operations (Fountain Committee) on June 14, 1977. It includes a statistical analysis that indicated the non-compliance with the guideline.

The NCI is involved with many other programs involving radiation technology and the radiologists constitute an important "constituency" of the NCI. They have been favored with over-representation on committees (as will be indicated subsequently) and with support for various programs involving the use of X-ray (such as the therapeutic adjuvant programs). Other NCI programs, such as the Centers Programs, encourage funding or justification for the purchase of costly radiological equipment. This is also documented in the testimony and supporting documents provided to the Fountain Committee.

Documentary evidence that radiologists feel threatened by the new scientific findings (and that the proponents of radiation-based programs at the NCI would likewise feel threatened) is provided by the reaction of radiologists reported in the Buffalo Courier Express. Exhibit 4 shows reaction to the same material (as published in the Journal of the American Medical Association) that was presented in the peer review of the Bross renewal proposal. As will be seen subsequently in the first section dealing with Point 4, the angry, defensive reaction of radiologists was the same in both cases. They feel personally and professionally threatened by the new facts and findings and this provides a strong motive for retaliatory action. Note that there is no serious effort at scientific rebuttal (just technical-sounding double-talk). There was the same reaction from radiologists during the peer review.

SUBSTANTIATION OF POINT 2

This section deals with the charge that "Both federal agencies had the means to stop further research by using the easily manipulated peer review process as an instrument for cutting off further funding for the two programs".

The use of the peer review instrument by the NCI will be described and documented in detail in subsequent sections. The available documentation for the ERDA employment of this instrument is more restricted, but what is available will be presented in this section. It will at least suffice to document Point 2 for ERDA. The peer review process is mentioned in the correspondence, memorandum, and letter in Exhibit 5 which constitutes (together with Exhibit 6) the totality of information received under the Freedom of Information request. Otherwise Exhibit 5 is rather uninformative.

There is some limited and censored information in Exhibit 6. A summary concerning the Mancuso program was prepared by Sidney Marks, M.D. The initial material (of the document labeled "Enclosure 2" has a heading labeled "Outside Reviews" (page 1, line 14) but there is nothing further. The spacing does not suggest that anything was censored out but that there was no outside review involved in this part of the document. The "Inside review" heading is followed by an extended description of components of the program and a section labeled "Evaluation." Thereafter there is a section labeled "Review" in which outside reviews are mentioned but the names have been eliminated and the reviews themselves were not provided. Therefore it is unclear whether the "Evaluation" reflects any outside review.

Although the "Evaluation" gets into some technical areas, there is one striking point which a non-expert reader can immediately see. In the list of "deficiencies in performance under the contract" there are such complaints as "reluctance to initiate analysis," "reluctance by the investigators to publish in edited journals," "quality of statistical expertise" and of the "statistical analyses." Each of these deficiencies was corrected in a very effective way. The analyses were carried out. The work was accepted for publication in Health Physics (an "edited journal"). Outstanding epidemiologists and statisticians were brought in for consultation in the persons of Dr. Alice Stewart and Mr. George Kneale. Dr. Stewart has been for many years a leading epidemiologist in the study of low-level radiation hazards, particularly pelvimentry hazards. A new statistical technology was developed to estimate latent periods and doubling times from the Hanford data, an important contribution to science.

The non-expert can see very clearly that the correction of the "deficiencies" did not make the slightest difference in the ERDA plans on page 4 of Exhibit 6. Nor can it be said that the correction of the deficiencies came after the decision was already past the point of no return. The date of Exhibit 6 is "January 8, 1976" but it refers to an "unedited document in connection with a presentation of a health physics symposium." This is the original version of the Health Physics article. It has Dr. Stewart and Mr. Kneale as co-authors. It uses the methodology and obtains the important results that appear (with small arithmetical changes) in the Health Physics article. Therefore ERDA knew that the deficiencies had been corrected. It also know that the scientific findings that were a threat to the nuclear industry had been obtained.

Under these circumstances, the statement on page 4, line 35 of Exhibit 6 in the section on "ERDA Plans for the Health and Mortality Study" reveals the intentions of the federal agency:

"The sensitivities associated with the study of workers in the nuclear industry constitute a compelling argument for providing an orderly transition from the current to a new principal investigator".

One possible translation of this into plain English would be: "The Mancuso findings could be disastrous for the nuclear industry and therefore control should pass to someone who can be relied upon to disparage the work of the previous principal investigator and subsequently kill the study."

That this objective would not be difficult to achieve is suggested by the section on page 4 labeled "Reviews". Starting on line 10, it is stated that:

"Outside reviews by (name censored) and (name censored) were unfavorable. Both reviewers felt that Dr. Mancuso's call for additional funding and enlarged study population is not justified".

One of the reviews was clearly not so bad. Thus it is stated that "(name censored) complimented the investigators on their careful, meticulous work to date". In peer review, one reviewer can do the hatchet job: "(name censored) recommended that the study be turned over to a different principal investigator". The information was not obtainable from ERDA but it would be relevant to know the name of this investigator and any subsequent connections of this person with ERDA as a consultant on this or other programs.

SUBSTANTIATION OF POINT 3

This section deals with the charge that "Both federal agencies used the peer review process to produce the desired verdict, primarily by selection of persons and panels whose professional interests were threatened by the scientific findings."

The documentation on this charge will have to be limited to the NCI because the Freedom of Information request to ERDA failed to produce a list of names or affiliations of the persons responsible for the ERDA decision. The only two identified individuals, Dr. J. L. Liverman and Dr. S. Marks, have long-standing involvement with ERDA or AEC. The motivation discussed in Point 1 applies to them.

The panel making the NCI decision, however, is clearly identified. A roster of the panel is given as the attached schedule, Exhibit 7. The panel is the Clinical Cancer Program Project Review Committee (CCPPRC). As its name suggests and the roster shows, the panel is almost entirely composed of M.D.'s, there being only one Mr. listed on the regular panel. One ad hoc member, Dr. Samuel Greenhouse, is a statistician and was the chairman of the site visit team. Of the 20 persons listed on this roster, 7 have titles which indicate a direct connection with radiation technology. Dr. Enrico Mihich has informed me that he absented himself from the session because of conflict of interest.

He is from RPMI, the institution submitting the grant proposal. He was, however, the only one who left to avoid conflict-of-interest. None of the radiologists saw any conflict of interest.

The conflict-in-interest is especially clear here because of the involvement of the research program under review in the controversy over the screening of women under 50 by mammography in the Breast Cancer Detection Demonstration Program (BCDDP). Radiologists participating in this review were on the opposite side of this controversy. Findings from sophisticated biostatistical and mathematical analyses ("metatechnology") which were carried out by the program up for renewal had supported the findings of Dr. John Bailar III[1] that the BCDDP benefit-to-risk ratio was around 1-to-1. They refuted the widely-publicized report of Dr. Rodney Withers of the M.D. Anderson Hospital that the ratio was 125-to-1. As Dr. Bross had publicly pointed out, Dr. Withers made a gross arithmetical mistake in using estimates from the BEIR report. Dr. Withers is one of the CCPPRC members.

The composition of the site visit team reporting to the CCPPRC is shown as Exhibit 8. It reflects the composition of the CCPPRC with 6 of the 9 members being M.D.'s. One of the M.D.'s. Dr. Phillip Cole, has credentials as an epidemiologist; the others have no special qualifications to judge the programs. Apart from the chairman there was one statistician and one academic geneticist. The composition of the committee will be further discussed in the substantiation of Point 4 where, in particular, the activities of Dr. Herman Libshitz, a radiologist from M.D. Anderson, will be discussed. Dr. Libshitz is a colleague of Dr. Rodney Withers and is also involved in the mammography controversy. The conflict-of-interest noted here will be shown in the material on Point 4 to have directly influenced, even disrupted, the site visit.

SUBSTANTIATION OF POINT 4

This section deals with the point that "The NCI site visit was disrupted by an angry radiologist".

Unlike most of the previous evidence, this section includes eye-witness testimony of the events at the NCI Site Visit of February 17, 1977 by Dr. Irwin Bross, the principal investigator of the renewal proposal under review. The composition of the site visit team was cited earlier in Exhibit 8. The agreed-upon agenda for the site visit is Exhibit 9. It shows there were 6 projects for review, 3 involving radiation research and 3 involving other topics. Three of the projects were to be reviewed in the morning, the rest in the afternoon.

This was a tight schedule. However, this research program had been operating for almost 8 years and all 6 projects were starting from new leads that had recently been published. The past performance of the program, such as the productivity shown in Exhibit 10 and Exhibit 11, was believed to be more than sufficient to justify renewal. These exhibits were part of the grant application for the renewal of Grant No. CA–11531 submitted in September 1976, copies of which were distributed in advance to all of the site visitors. An update of publications was distributed at the site visit and is included in Exhibit 10.

The agenda was the first casualty of the attack on the first project led by an angry radiologist, Dr. Herman Libshitz. This project was defended (Exhibit 9) by Mr. Natarajan and involved the material on genetic damage from ordinary diagnostic radiation (Exhibit 2) that was subsequently to be published in the Journal of the American Medical Association (though this was not known at the time of the site visit). The attack continued all morning and was still going strong when the site visitors finally adjourned for lunch.

The questioning, led by Dr. Libshitz, returned over and over again to the kind of questions that amateur epidemiologists always ask. Dr. Libshitz was mainly assisted in his efforts by two other visitors. One was Dr. Wolff Kirsch who, as ad hoc member of the parent committee, was supposed to plead the case for this program to this committee. Another was an academic geneticist, Dr. Charles Sing, whose research has received support from ERDA–AEC funds although this is not a very frequent source of support for academic geneticists.

The questioning employed such tactics as asking an elementary question and then interrupting the reply with another question. For example, Mr.

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[1] Editor, Journal of the National Cancer Institute.

Natarajan was repeatedly asked about the obvious distinction between the delivery of X-rays to the mother prior to pregnancy and during pregnancy. It does not take a geneticist to realize that if the effect is leukemia in the child, then in one instance the genetic damage must be to the mother's cells and in the other instance to the fetal cells. Dr. Sing kept insisting that Mr. Natarajan did not understand the distinction although the latter had just completed an article comparing the two situations.

After the first few minutes, it should have been clear to the Chairman that Dr. Libshitz and his cohorts had come to kill the program and that the Chairman had to act firmly if there was to be a fair hearing. The amiable but ineffectual Chairman, Dr. Samuel Greenhouse, was unable to control the proceedings. As a result, Dr. Libshitz accomplished his purpose. The schedule was completely disrupted. The bitter first session set up an adversary relationship between the reviewers and those reviewed. The negative tone, once set, ran through the rest of the site visit. The scientifically irrelevant but adversive "putdowns" got into the pink sheet, though the responses did not. Letting Dr. Libshitz achieve this purpose was like allowing a tobacco company representative to disrupt a site visit on research on smoking hazards.

It should again be noted that rigging a site visit does not require that all visitors be hostile. A few determined persons can control a panel that has a majority of fair-minded but uninvolved scientists. Here, for example, the one person who was qualified to speak, Mr. Jablon, said very little at the visit or in the pink sheet. Mr. Jablon was the working statistician on the Japanese A-bomb study. The only M.D. with epidemiological credentials, Dr. Philip Cole, intervened several times to try to correct Dr. Libshitz's misconceptions about epidemiology. He gave up, however, after a few fruitless attempts. Dr. Greenhouse, the chairman, was completely out of his depth.

The end result was that the site visit was dominated by persons who had neither epidemiological, biostatistical, nor mathematical competence to evaluate the methodology of the radiation studies. This particular site visit got completely out of hand, which is somewhat unusual. However, lack of competence on the part of reviewers is not uncommon in peer review operations.

This section deals with the point that "The resultant 'critiques' supporting the verdict are little more than selected adversive statements that are scientifically irrelevant 'put downs' of the programs".

Failure of ERDA to provide documentation for the "critiques" used in the Mancuso decision despite requests under the Freedom of Information Act necessitate the use of the NCI "pink sheet" where this documentation is available. This document is appended as Exhibit 12.

While the nature and language of Exhibit 12 is similar to other NCI pink sheets, it is longer than usual. Instead of a single sentence or paragraph, the document goes on for pages. It contains the usual cliches or "putdowns" that are used in rejecting epidemiological studies. These ordinarily tend to be such vague generalities that, although they may sound devastating to a non-expert reader, the statements can be "safely" made about almost any study.

Perhaps because of the additional length, this pink sheet is more informative than the usual one. The reviewers indulged in "overkill", the inclusion of more deleterious statements than were needed to kill the proposal. Such statements are more specific because the intent is to deeply wound the investigators under review (who might shrug off generalities). The "overkill" stands out especially clearly because of the hypocritical praise of the principal investigator that was put in as a precaution at the top of page 12 or Exhibit 12. The "overkill" statements are useful here for two reasons. First, they are refutable by factual evidence. Second, they show malicious intent.

The natural reaction of a scientist to a catalogue of adversive statements is to attempt a point-by-point rebuttal. This will not be done here for two reasons. First, the technical-sounding adversive statements tend to be "safe" cliches which can almost always be used as "putdowns" for a study and are in this sense "unanswerable". Second, by trying to answer the "putdowns", a scientist gives the non-expert reader the impression that there is a genuine disagreement between experts. The non-expert may feel then that there is no hope of resolving such a disagreement.

Fortunately the publication of the papers (which are the main target of criticism in the ERDA and the NCI peer reviews respectively) gives a non-expert a way to avoid the technicalities. After reading the seemingly devastating "scientific" criticisms, the non-expert might reflect that if even half of these "putdowns" had any scientific validity, it would be extremely unlikely that these articles would ever have been published in journals as conservative as the Journal of the American Medical Association or Health Physics. The non-expert might also note that the bitterly attacked material in the audit leukemia study (Project V of Exhibit 9) has also been accepted for publication by the Journal of Medicine.

On the other hand, a brief review of a few of the injudicious "overkill" statements suffices to eliminate any pretense of an objective scientific evaluation of the studies. The first example is on page 11, line 37 of Exhibit 12 where it is clearly not needed in the context of the discussion. This spiteful statement is:

"The justification for the core budget, however, seems to have been based on the past performance of the principal investigator. His past work was considered by the review as above average. Yet, little progress seemed to have been made during the past three years."

This statement appears in connection with requests for funds covering administrative costs (e.g. part-time administrative assistant and secretary), not scientific functions. This "overkill" statement is directly refutable by factual evidence that was supplied to the site visitors, a list of approximately 100 publications produced by the team in the last three years (see Exhibit 10). Several major scientific findings were also listed (Exhibit 11). A crude articles-per-dollar index can be used for comparison with other NCI programs. It is unlikely that any proposal approved and funded by the parent committee (CCPPRC) had even half the productivity-per-dollar of the grant under review. Indeed, this productivity cannot be matched by very many NCI grants reviewed in any category.

An even more informative example of the way the "instant experts" or review panels "put down" work which they can't even understand is this pontification from page 13, line 4 of Exhibit 12. This is in the Summary and therefore would involve both panels.

"As for the group's reported progress in mathematic modeling, namely, Dr. Bross's development of the deep mathematical model, it was not clear to the reviewers that the work thus far has led to any deeper understanding of the cancer process or relationships than has been gained by conventional analysis."

This judgment may sound impressive until it is recalled that it is a pronouncement by M.D.'s (and Ph.D.'s who are not strong mathematicians) on research that has gone on for more than ten years and has produced more than a dozen mathematical papers. The ability of the reviewers to read (let alone criticize) this work can be readily judged by any non-expert reader. An intelligent reader is on par with an M.D. when it comes to reading about sophisticated mathematical models. Exhibit 13 shows the nature of this research. The two papers by Dr. Leslie Blumenson provide the underpinning for the Bross and Blumenson paper which contains the evaluation of mammographic screening which refuted the radiologists. (Personal aside: Dr. Bross will personally and publicly apologize to any member of the review panels who will take and pass a short written test of comprehension of these papers). This statement illustrates the willingness of this panel to make adversive statements on material that they greatly dislike but don't understand. It also shows that the pink sheet is a basically fraudulent document.

Another example of "overkill" illustrates that even "safe" cliches happen to fail here. On page 13, line 1 of Exhibit 12 there is a denegration of the investigators data that should really hurt:

"A third major defect seemed to be the lack of a systematic attempt to validate information in records, procedures which are part of all sound epidemiologic studies."

As was repeatedly emphasized orally and in writing, the Tri-State data that was analyzed here comes from a study set up almost 20 years ago by Dr. Abraham Lilienfeld.[1] The arrow aimed at Dr. Bross hits an innocent but distinguished epidemiologist. This safe cliche fails here because the Tri-State Survey is famous in its own right as the best data base of its kind. It has been used in more than a dozen different published studies by well-known epidemiologists. This statement in the pink sheet shows that the reviewers had not done their homework and weren't listening.

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[1] Distinguished Professor, The Johns Hopkins University.

A non-expert who reads the pink sheet for "tone" (as opposed to content) will note that while the tone is relentlessly negative for the radiation projects, in other projects it sounds more positive or even encouraging. This is evidence of the intention of the reviews to try to shift the direction of research away from radiation hazards to some safer area. This intent (which is contrary to NCI guidelines) is made even more explicit on page 2, line 10 of Exhibit 12 (the crucial last line of the resume):

"In recommending disapproval of the proposal, the Committee members expressed the hope that the applicants will reconsider this latter direction for their future studies."

The "latter direction" is indicated in the previous sentence:

"Given its present monolithic structure, where this group seems most likely to make worthwhile contributions is in the conduct of straight, epidemiologic investigations."

Clearly the doctors reviewing the studies regarded the study of cigarette hazards as "epidemiology" and the study of occupational hazards as "epidemiology" but the study of radiation hazards produced by doctors is not "epidemiology" but "medicine". Hence, one translation of the two above statements into plain English is: "If you want any future NCI funds, stay away from sensitive research on radiation hazards".

In sum, the cited evidence from the pink sheet shows that it was window-dressing for the verdict stopping the radiation research. There is no semblance of an objective scientific evaluation. In this respect, however, the operation of peer review machinery in this instance is not entirely unusual.

SUBSTANTIATION OF POINT 5

The purpose of point 5 is to point out some of the implications of the actions taken by the two federal agencies.

The termination of important research in progress deprives the public of potentially important new scientific knowledge of the hazards of low-levels of ionizing radiation. This knowledge is of vital importance both in protecting the public health and in making realistic decisions on energy policies.

The cut off of funding to the two scientific programs will discourage American scientists from doing research in senstive areas—particularly areas with major fiscal effects as well as health effects. This government intervention to suppress the truth in a sensitive area is, unfortunately, exactly what we have accused other countries of doing.

Finally, use of the peer review machinery that brings in members of the scientific and medical community to provide respectable "cover" for a process that has been rigged to produce a desired verdict leads to the erosion of the integrity and credibility of these communities. The sincere scientists and physicians used as dupes by the agencies have the best of intentions. This does not, however, exempt them from responsibility. Their reluctance to speak out has encouraged corrupt use of peer review machinery by "Big Science" federal agencies.

The charges against ERDA and the NCI are not necessarily charges in the legal sense. It is not clear what, if any, laws are broken in rigging a peer review to produce a desired verdict. What is clear is that this is against the public interest and against the long-term interests of the scientific and medical communities as well. If legislation is needed to stop these abuses, then this would seem a high priority task for a President and a Congress with a public commitment to reform.

[The following information was subsequently received for the record:]

ROSWELL PARK MEMORIAL INSTITUTE,
DEPARTMENT OF HEALTH, STATE OF NEW YORK,
Buffalo, N.Y., August 24, 1977.

WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Russell Senate Office Building, Washington, D.C.

DEAR MR. MAGNUSON: This is in response to your letter of August 15, 1977 containing further questions with respect to my testimony on June 17, 1977. I am submitting five copies of my responses as requested. As you know, I had already submitted a response to a question asked at the hearing by Senator Stevenson documenting my remark that "These major scientific achievements in the past year might seem to deserve a Nobel Prize, but, in point of fact, in both cases the reward was a cutoff in the funding of the research by angry radiation technologists at ERDA and angry radiologists at NCI."

I believe that the efforts to suppress publication of research on the hazards of low levels of ionizing radiation, efforts which date back to the AEC's efforts to protect weapons testing from the public reaction to fallout hazards, is a matter which the committee should further look into. It is disgraceful for agencies in the federal government to try to keep the truth about these radiation hazards from the general public.

Very sincerely yours,

IRWIN D. J. BROSS, Ph. D.,
Director of Biostatistics.

NOTE.—The statements made here represent the views of individuals in the Biostatistics Department and should not be construed as officially representing Roswell Park Memorial Institute for Cancer Research.

Enclosure.

Question 1. In his testimony before this Committee, Dr. Russell H. Morgan of the American College of Radiology has indicated that a paper by Smith, Pike, and Hamilton of the University of Oxford ". . . raises serious questions with some of the premises and assumptions . . ." which you make in your paper alleging serious biological effects for exposure levels in the vicinity of one rad. What is your response to the specific points raised by these authors in their paper?

Answer. The cited paper (Smith et al.) does not deny that the Tri-State Survey data shows clear effects but offers a different explanation (e.g. "counterhypothesis") to account for them. The underlying idea of their counterhypothesis is that the "indicator diseases" might be, in effect, precursors of leukemia. This counterhypothesis is flatly contradicted by the facts since, in the absence of radiation, the "indicator diseases" and leukemia are independent. The association arises when there is radiation because both the "indicator diseases" and the "leukemia" are caused by the radiation (as will be explained in more detail in the sequel).

Another point about biostatistical technology for complex epidemiological data is also involved. This technology is like an optical instrument in that it allows us to read the messages in data that would otherwise be obscured by random variation. The more powerful the technology, the more clearly the message can be read. Therefore, when someone using a powerful "microscope" (as in the JAMA paper (finds a pattern and someone else (as Smith et al.) using a "hand lens" does not, there is really no contradiction. An inferior statistical analysis will miss effects that a good one can detect. This happens all the time.

It happens in the Smith et al. paper. It also occurred in criticism of the Mancuso, Stewart, and Kneale findings. Half a dozen incompetent analyses of the same data found nothing (although competent analyses had no trouble demonstrating real effects). One moral is that it is pointless to delay public health action until "all the experts can agree". All the experts never agree. There are a relatively few competent experts but plenty of incompetent ones and they won't agree (whether it is statistics or any other subject).

So my response to the ". . . serious questions with some of the premises and assumptions . . ." of Dr. Russell H. Morgan of the American College of Radiology is that these questions were very clearly answered in the recent article in the Journal of the American Medical Association. In fairness to Smith et al., it should be noted that the cited paper did not involve the analysis in the JAMA paper. It concerned a very much earlier paper of ours which used a less illuminating analysis. The JAMA paper involved a new biostatistical technology which uses a mathematical model to characterize the hypothesis under test and all assumptions are precisely stated. The mathematical model is shown in Table 1 and, as can be seen from Table 4, gives an excellent description of the actual data. One advantage of an explicit mathematical model is that there are no hidden assumptions and the assumptions of the model are directly tested. Note that when an assumption is empirically validated, it is no longer an assumption.

The Smith criticism of the earlier paper (which used a general-purpose biostatistical technology rather than the much more powerful mathematical model) involves a counterhypothesis that the "indicator diseases (listed in the article) are related to leukemia irrespective of whether or not there was radiation delivered to the fetus. The data and model shown in Table 2 show that the counterhypothesis is contradicted by the data, The simple model assuming independence of the "indicator diseases" and leukemia works fine when there is no radiation. This can also be seen for the other two age groups in Table 4 when there is no report of radiation. In other words the assumption of independence in the absence of radiation is not an arbitrary one but rather describes the actual data.

There is a relationship between the "indicator diseases" and leukemia when there is a report of radiation to the mother during pregnancy, or (in data not shown here but available) when there is a report of x-ray to the mother or father prior to conception. The explanation is simply that the radiation produces breakpoints in the DNA (or genetic damage) which eventually leads to deficiencies in the host-defense machinery of the child. These deficiencies may be expressed as "indicator diseases" or leukemia or both. As Table 3 shows the mathematical model, extended to include the concept of genetic damage, accounts for the data when X-ray is reported.

Question 2. What is current "state of the art" in diagnostic x-ray equipment? What reduction in patient exposure could be achieved if modern x-ray equipment were to replace the existing inventory?

Answer. The "state of the art" in diagnostic x-ray equipment is in a "state of flux." Many claims are made for dosage levels and safety. Most of these claims are false or misleading. If obsolete systems (not just hardware but also films and techniques) were replaced with effective low-dose systems (and if unnecessary x-rays were eliminated), the radiation exposure of the population could be cut by a factor of 10 within 2 years. Unfortunately, the kinds of standards usually legislated do little or no good. The trouble is that control of hardware is much less important than control of the way the overall system is used in practice. Operations in the field are harder to control (although it can be done).

For example, after the mammography furor (in which I was involved) the manufacturers and radiologists claimed very low dosages for their new films and equipment systems. These claims were consistently refuted by radiological measurements made in the field by the National Cancer Institute. Although levels of exposure well under one rad were often claimed, the actual measured levels of exposure for mammograms was usually well over one rad and often two to four rads. These false claims are made because it is easy to lie to the public in a technical jargon. There are a lot of technical tricks which reduce the "reported" exposure without reducing actual exposure. For instance, exposures are often reported on a per film basis. In fact, more than one film is required to do mammography. Again some "low-dose" systems required repeated shots to get a readable film.

The claims about safety are equally misleading. Kodak advertised in *Science* and in *Scientific American* that the benefit-to-cost ratio in the mammographic screening program (BCDDP) was 125 to 1 when in fact it is about 1 to 1 overall. Equally false are the claims for CAT scanners. These are supposed to be "safe" and are said to deliver "about the same amount of radiation as an ordinary x-ray." In fact, the CAT scanners deliver 60 or more times more x-ray. This is a dose capable of producing leukemia in perhaps 10 percent of the men who are exposed to it (this estimate is based on unpublished work of ours). The safety claims for CAT scanners are based on the myth that fractionalization of dosage makes the genetic damage disappear—a point specifically refuted in the JAMA paper.

The difference between CAT claims and truth is this. The CAT essentially puts the patient on a spit and barbecues him with x-ray. Because of the rotation, the amount of x-ray absorbed by 1 cc of tissue is a rough equivalent to the amount of x-ray absorbed by 1 cc of tissue in ordinary diagnostic radiation. The "rads" are calculated on a per cc basis. However, the total dose—which is what counts—is much greater. With rotation, all of the patient circumference is exposed to x-ray instead of just one narrow field. Hence total CAT exposure can be more than 100 times greater than ordinary diagnostic x-ray despite the claims that have been made. This heavy dosage results in a high risk of leukemia in the men who are scanned.

While I am at it, I might say that the claims for benefits for CAT scans are simply lies (except for cranial vascular lesions). The diagnosis of internal cancers by CAT scans has been hailed as a great advance but there is no benefit to the patient. The reason is simply that a CAT scan can only pick up a cancer that is the size of a small organ (because this is the limited resolution of the scan). By the time a patient has internal cancer the size of a small organ, the disease has already generalized. The patient is going to die from it whether or not a diagnosis is made. On the other hand, most of the patients sent through the CAT scanners will not have cancer at that time but a lot of them will get cancer 7 or 8 years later from the CAT scan.

As I said in my congressional testimony to the Fountain Committee of the House as well as to the Senate Committee, iatrogenic cancer is an increasingly important factor in the cancer death rate in this country. While other doctors are responsible for some iatrogenic cancer, the radiologists are responsible for most of them. Technical advances can reduce exposure but there are so many false claims it is hard to know which ones will do the job.

Question 3. During your oral testimony you referred to a survey reported by the American Medical Association on the practice of "defensive medicine." Please provide the Committee with the citations to this study.

Answer. My testimony was based on newspaper stories concerning a survey on defensive medicine taken by the American Medical Association. The original report appeared in the American Medical News on March 28, 1977 in the Impact Section on page 3. The librarian at the American Medical Association has kindly promised me a copy of the report and I will forward it when it arrives.

On the question of unnecessary x-rays and the reasons for them, I might have cited the Bureau of Radiological Health estimates which have been around for some time. These are given in the enclosed letter to me from Dr. Gooloo S. Wunderlich. He agrees that there is a major problem: 290 million x-rays each year, 30 percent to 40 percent of them unnecessary, costing an unnecessary 2 billion dollars. These estimates are much larger than my independent estimates because they include both dental and medical x-rays while my estimates were for medical x-rays. Thus while the above figures show about 100,000,000 unnecessary x-rays and mine "only" 10,000,000 this is about the right ratio of medical to all x-rays.

By way of explaining why so many unnecessary x-rays are given, both Wunderlich's letter and my reply to it (both enclosed) deal with this point. Basically it is that neither the doctors calling for the x-ray or the radiologists delivering it have any conception of what they are doing to our most precious resource—the genetic material of human beings. The individual risks are small and easily missed—perhaps a 1 percent to 5 percent risk of producing serious genetic damage that is detectable with our data and technology. But when such risks from unnecessary x-ray are calculated on a population instead of a patient basis we are talking about 100,000 to 500,000 persons affected each year.

The notion that low level x-ray is "harmless" still pervades the medical profession and it is the price we pay for the policy of suppression of research and reports of low level radiation—hazards by AEC starting in the 1940's and continuing (with ERDA and NCI) right down to the present.

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Genetic Damage From Diagnostic Radiation

Irwin D. J. Bross, PhD, N. Natarajan, MS

• Using the data from the Tri-State Leukemia Survey and a mathematical model, the hypothesis that low levels of diagnostic radiation produce severe genetic damage that is expressed in the child of the exposed person as leukemia and other diseases is tested. It is estimated that for about 1% of the exposed persons who are affected by radiation, there is a 50-fold increase in the risk of leukemia and a five-fold increase in certain other diseases.

(*JAMA* 237:2399-2401, 1977)

THE WORK of Stewart and colleagues[1-2] and others pointed out the dangers of diagnostic radiation years ago, but exposure to diagnostic x-ray in the United States and other nations has, if anything, increased. This communication deals with diagnostic x-ray, typically in the range from 0.5 rad to 5.0 rads, and the consequences to the children of the persons exposed to the radiation.

The rationale of the present analysis evolved from a series of previous analyses[3-4] of the Tri-State Survey data. It was originally found[3] that when there was a report of radiation exposure to the mother before or during pregnancy or to the father prior to pregnancy, the risk of leukemia was increased. The increase was modest, on the order of 50% (relative risk, 1.5). It was later found that in the general population of children, there is a susceptible subgroup (defined by certain indicator diseases) where the risk of leukemia increased far more than for the rest of the children.[3-4] Here, the increase was on the order of 500% (relative risk, 5).

The working hypothesis of the present analysis was that the radiation exposure produced both the indicator diseases and the leukemia. If so, there would, in theory, be a subgroup of persons affected by the x-ray exposure in whom the risks of the indicator diseases and of leukemia would be still more substantially increased.

The indicator diseases are asthma, urticaria, eczema, pneumonia, dysentery, and rheumatic fever. Radiation during pregnancy includes any radiation delivered to the trunk as well as any radiation to the fetus. Preconception radiation to the mother and father includes x-ray to the trunk, and excludes dental and extremity x-rays. Persons receiving one type of exposure may also have received another. Dosages are usually less than 1 rad per year.

Methods and Procedures

To test the working hypothesis, a new method for analysis of the Tri-State data was developed. It was based on a mathematical model that described the population at risk and also embodied the specific working hypothesis under test expressed in a mathematical language (Table 1).

The population at risk in the Tri-State survey were the persons in designated areas of three states during a three-year period.[3,4] The aim of the survey was to interview persons in all households where there was a case of leukemia during this period and in a stratified random sample of the households where there was no leukemia. The radiation exposure considered is reported by interview, is validated by medical records, and is one of about 50 factors considered in the survey. Only data on the children (persons between 1 and 15 years of age) are analyzed, and the initial examples will consider the children between 1 and 5 years. Only the radiation to the parents of the leukemic or nonleukemic child is reported. The first step is to characterize the data in the series of persons not exposed to radiation in mathematical language.

For this purpose, the following specific numerical parameters are used: (1) number of children 1 to 4 years of age (700,000), (2) probability of leukemia (6 per 100,000), (3) number of years in survey (three), (4) sampling rate (1 in 3,255), (5) proportion not radiated (24.3%), and (6) probability of indicator disease (.0943). The first two parameters (1 and 2) come from census data and vital statistics. The second two (3 and 4) are design parameters of this study. The last two (5 and 6) are estimated from the random sample data, but only parameter 6 is estimated from the body of the tables. In addition to the parameters, the assumption is made that the probability of an indicator disease and the probability of leukemia are statistically independent.

Results

The expected values for each combination of diseases for the children

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From the Roswell Park Memorial Institute, Buffalo.

Reprint requests to Roswell Park Memorial Institute, 666 Elm St, Buffalo, NY 14263 (Dr Bross).

aged 1 to 4 years in whom there was no report of x-ray exposure are (1) with indicator disease and leukemia: 700,000 × .243 × .00006 × 3 × .0943 = 2.9; (2) with no indicator disease and leukemia: 700,000 × .243 × .00006 × 3 × .9057 = 27.7; (3) with indicator disease and no leukemia: 700,000 × .243 × .99982 × .0943 × 1/3,255 = 4.9; and (4) with no indicator disease and no leukemia: 700,000 × .243 × .99982 × .9057 × 1/3,255 = 47.3 ($\chi^2 = 0.03$).

The observed counts and the expected numbers calculated from the model for each disease combination are given in Table 2 for the children in the 1- to 4-year age group where there was no report of parental x-ray exposure. For a mathematical model, as for any other theory, the acid test is whether the theory fits the facts. The agreement of the observed and expected values shows that the model fits the data satisfactorily. In effect, the assumption of independence is validated. A more formal test (χ^2) is also presented.

The same model fails to fit the facts for the series where there is a report of x-ray to the mother during pregnancy. This is shown in Table 3. For reasons explained in the sequel, the previous model has been used to predict 99% (the unaffected) of the population. The disparity between the 3.4 expected and the 12 cases observed is apparent ($\chi^2 = 28.5$). this leads us to reject the original model and to extend the theory as follows: When a mother is exposed to radiation during pregnancy, genetic damage occurs in only a small proportion of babies (the affected children). However, this genetic damage will later be expressed as increased risk of certain childhood diseases.

The extended theory involves three additional parameters: (7) the proportion affected by the x-ray (1%), (8) the increased risk of indicator diseases (relative risk, 5), and (9) the increased risk of leukemia (relative risk, 50). In practice, there is really a single key parameter that is the product of 7 and 9. Parameter 8 is sharply restricted by the requirement that the probability of an indicator disease in the exposed series cannot exceed unity. The proportion with a report of x-ray to the mother during pregnancy is .289.

The expected values are (1) with leukemia and indicator disease: 700,000 × .289 × 00006 × 3 × 50 ×

Table 1.—Algebraic Characterization of Mathematical Model

Case 1: No Radiation Exposure Reported

The notation used is as follows:

X_1=Age group (0=1-4 yr, 1=5-9 yr, 2=10-14 yr)
X_2=Occurrence of indicator disease (0=No, 1=Yes)
X_3=Occurrence of leukemia (0=No, 1=Yes)
$D_0(X_1)$=Probability of at least one indicator disease
$L_0(X_1)$=Probability of leukemia
K=No. of yr in survey

The probability of a given status with respect to indicator disease, leukemia, and age is

$$P_0(X_1, X_2, X_3) = [D_0(X_1)]^{X_2}[1-D_0(X_1)]^{1-X_2}[L_0(X_1)\cdot K]^{X_3}[1-L_0(X_1)\cdot K]^{1-X_3}$$

Assumption of independence (algebraic form)

The expected numbers in a 2×2 table can be calculated using the following:

$N(X_1)$=No. of children in population in age group X_1
$H_0(X_1)$=Proportion with no radiation exposure
S=Sampling rate in random sample

So that $N(X_1)\cdot H_0(X_1)$ is the total number with no radiation exposure reported in the population in the age group X_1, and then the expected numbers for the individual cells in the 2×2 table are

$$E_0(X_1, X_2, X_3) = N(X_1)\cdot H_0(X_1)S^{1-X_3}\cdot P_0(X_1, X_2, X_3)$$

(Note that when there is leukemia, the sampling rate is 1.)

Case 2: X-ray During Pregnancy Reported

The notations used here are as follows:

D_1=Probability of indicator disease in group exposed to radiation and affected (ie, suffered genetic damage)
L_1=Probability of leukemia in affected group
A=Proportion affected by radiation exposure
H_1=Proportion with radiation exposure
So that $D_1 = D_0\cdot R_D$ and $L_1 = L_0\cdot R_L$ where
R_D=Relative risk of indicator disease
R_L=Relative risk of leukemia

As before, $N(X_1)\cdot H_1(X_1)$ is the total number with reported x-ray during pregnancy in the age group X_1 in the population.

Now, the probabilities for individual cells in the 2×2 table with radiation exposure contain two parts: The probabilities for those (1) who were exposed to radiation but not affected, and (2) who were affected by radiation. The probabilities for the former are the same as those with no radiation exposure reported, and the probabilities for the latter are

$$P_1(X_1, X_2, X_3) = [D_1(X_1)]^{X_2}[1-D_1(X_1)]^{1-X_2}[L_1(X_1)K]^{X_3}[1-L_1(X_1)\cdot K]^{1-X_3}$$

So, the expected values for the group with exposure to mother's radiation during pregnancy are

$$E_1(X_1, X_2, X_3) = N(X_1)H_1(X_1)S^{1-X_3}\boxed{[(1-A)P_0(X_1, X_2, X_3) + A\,P_1(X_1, X_2, X_3)]}$$

Dependence due to x-ray as common cause of both kinds of disease

Table 2.—Observed and Expected Counts in Children Aged 1-4 yr*

	Indicator Disease, No.	
	No	Yes
Leukemia		
Observed	27	3
Expected	27.7	2.9
No leukemia		
Observed	48	5
Expected	47.3	4.9

*Parents did not receive x-ray exposure.

The diseases are independent when there is no report of radiation

Table 3.—Model and Adjusted Model for Observed and Expected Counts in Children Aged 1-4 yr*

	Model Indicator Disease, No.		Adjusted Model Indicator Disease, No.	
	No	Yes	No	Yes
Leukemia				
Observed	45	12	45	12
Expected	32.7	3.4	42.3	12.0
No leukemia				
Observed	60	3	60	3
Expected	55.7	5.8	56.0	6.1

*Parents received x-ray exposure.

The diseases are ne when there is a [illegible]

.0943×5×.01=8.6; (2) with leukemia and no indicator disease: 700,000×.289 × 00006 × 3 × 50 × .5285 × .01=9.6; (3) with no leukemia and indicator disease: 700,000×.289×.991×.0943×5×.01×1/3,255=.29; and (4) with no leukemia and no indicator disease: 700,000×.289×.991×.5285×.01×1/3,255=.33. The expected values given in the adjusted model in Table 3 are obtained by adding the expected values for the affected persons (1%) with those of the unaffected (99%). The χ^2 values equal 28.1 (original model) and 2.02 (adjusted model).

The results for the adjusted model are shown in Table 3, where the affected and unaffected subseries have been recombined. The fit is satisfactory by inspection or by the usual χ^2 criterion.

The mathematical model has been illustrated, for simplicity, by the children aged 1 to 4 years. The same approach can now be used to predict the counts for the children in the 5- to 9-year and 10- to 14-year age groups. The results are presented in Table 4. As can be seen by eye or by χ^2 analysis, the theory satisfactorily fits the facts.

Using the procedure for calculations explained in Table 3, the observations for the children in the 5- to 9-year and 10- to 14-year age groups and the combined group are predicted. For the age categories of the group with no reported radiation, γ^2=0.03, 1.5, 2.4, or 3.9 (df=3). For x-ray during pregnancy, corresponding χ^2=2.0, 0.7, 0.4, and 3.1 ($df \geq 3$).

Comment

For genetic damage to result from exposure to radiation during pregnancy, the lesions in the DNA would have to be in the cells of the fetus, probably in cells involved in the blood-forming systems. Alternative explanations for the results in Table 4 might therefore involve effects of radiation on developmental processes. While such effects are also possible, the explanation in terms of genetic damage is strongly supported by analyses using the same model that have been made for the data on radiation delivered to the mother or father during a period prior to pregnancy.

Table 4.—Extended, Adjusted Model for All Age Groups

Age Group, yr	No Radiation		Radiation	
	Indicator Diseases, No.			
	No	Yes	No	Yes
1-4				
Leukemia				
Observed	27	3	45	12
Expected	27.7	2.9	42.3	12.0
No leukemia				
Observed	48	5	60	3
Expected	47.3	4.9	56.0	6.1
5-9				
Leukemia				
Observed	13	3	11	7
Expected	18.2	3.0	14.0	6.9
No leukemia				
Observed	79	13	53	8
Expected	77.8	12.6	51.2	8.8
10-14				
Leukemia				
Observed	8	1	4	4
Expected	11.9	2.6	5.1	3.8
No leukemia				
Observed	72	16	30	6
Expected	68.8	15.3	27.9	6.5
Total				
Leukemia				
Observed	48	7	60	23
Expected	57.8	8.5	61.4	22.7
No leukemia				
Observed	199	34	143	17
Expected	193.9	33.0	135.2	21.4

While these results will be presented in another communication, they are very similar to those in Table 4. The models give a satisfactory fit to the data on preconception exposures, with most of the parameters similar to those reported here. The principal difference is that the estimates related to the genetic damage are somewhat smaller. Mother's preconception radiation shows about 80% of the effect shown here, and exposure of fathers, about 50% of this effect. For these data, there would be no sensible alternative to an explanation in terms of genetic damage to the parental DNA.

In sum, there is clear prima facie evidence that exposure to the low levels of ionizing radiation can produce a drastically increased risk of leukemia and other diseases in the children of persons exposed to these levels. For the minority of exposed persons who are affected by the radiation, there is a 50-fold increase in the risk of leukemia and a five-fold increase in certain other diseases.

These findings refute a dogma that is often cited by radiologists who claim that diagnostic radiation is harmless. According to this dogma, genetic damage (like acute side effects) will vanish when the dosage of radiation is sufficiently fractionated. This human data on exposure to ordinary diagnostic radiation show that the genetic damage still occurs even with fractionalization.

The genetic damage to a population is roughly proportional to the total dose of radiation delivered to the population. However, it is spread more thinly through the population when there is fractionalization. Hence, it takes first-rate data and sophisticated biostatistical technology to detect the effects. Fractionalization creates the illusion that the genetic damage has disappeared, when, in actuality, the genetic damage to the population is, if anything, increased. "Out of sight, out of mind" is a dangerous precept when genetic damage in a population is involved.

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Therefore, the indicator diseases are not simply precursors of leukemia

—independent—
of radiation

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Irwin Bross

BUFFALO COURIER-EXPRESS, Tuesday, March 29, 1977

Fear of Lawsuits Boosts MD Bills

© New York Times News Service

NEW YORK — Three out of four American physicians are practicing "defensive medicine" by ordering extra tests for patients to protect against potential malpractice suits, according to an American Mecical Assn. (AMA) poll.

Medical bills are rising as a result of the doctors' action, according to poll results published in the American Medical News, a nonscientific newspaper that the AMA publishes in Chicago.

Many doctors have given anecdotal evidence that the practice of "defensive medicine" is rising. But the poll, taken last month, is one of the few studies to have documented the trend on a statistical basis.

By the phrase "defensive medicine," doctors mean the ordering of X-rays, blood and other diagnostic tests, not for the patient's medical benefit but to provide an adequate medical-legal defense if the patient sues.

The New York State Medical Society has said that, at an extra cost of about $30, "many doctors are routinely X-rayed swollen ankles even when they're 99 per cent sure it's just a sprain and not a break or a fracture."

In some instances, doctors maintain, the tests not only represent an extra cost but also pose a risk to the patient.

The AMA poll showed, among other things, the following:

—Virtually all physicians expressed a greater awareness about the prospects of malpractice suits than in years past. Physicians younger than 35 seemed least concerned about the possibility of being sued for malpractice.

—About half the physicians responding said they were ordering one or two extra tests for each patient; about one-quarter of the doctros were ordering three or four more tests; 10 per cent were ordering five or six additional precautionary tests, and 5 per cent ordered more than six extra tests.

—Three out of five said they had raised their fees within the last year because they were paying higher malpractice premiums. About half the doctors raised their fees 10 per cent or less; 30 per cent raised fees 11 to 20 per cent, and 15 per cent increased their charges 21 to 30 per cent.

TODAY'S WORLD

"An emergency, Dr. Smith, an emergency — call your attorney!"

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH,
Washington, D.C., July 22, 1977.

IRWIN D. J. BROSS, Ph. D.,
Director of Biostatistics, Roswell Park Memorial Institute, Department of Health, State of New York, Buffalo, N.Y.

DEAR DR. BROSS: Your letter of June 20, 1977 to Secretary Califano proposing a "Certificate of Necessity" for x-ray examinations has been referred to this Office for reply.

While interesting, the proposal does not appear to be practical to introduce at this time. It is extremely difficult to develop objective standards for determining the need for each kind of x-ray examination without impinging inappropriately on the physician's judgment.

We agree that there is a major problem in unnecessary x-ray examinations and, certainly, the present climate of malpractice and the availability of third-party reimbursement has contributed to the increased use of x-rays. FDA estimates that approximately 30–40 percent of annual diagnostic x-rays (estimated at 270 million medical and dental) are unnecessary with respect to the patient's clinical requirements and that the cost of these unnecessary x-ray examinations is approximately $2 billion annually.

We believe that the unnecessary radiation exposure can be significantly reduced by correcting product defects, making simple improvements in the techniques of x-ray users, and intensifying education efforts to improve the physician's judgment as to the necessity of ordering x-ray examinations. These approaches form the basis for FDA's National X-Ray Control System. Through local PSRO peer review and continuing educational efforts of health care personnel, better radiation usage practices are evolving.

We clearly need, however, much better means to decide when an x-radiation procedure is warranted based upon valid criteria for the different types of diagnostic procedures and also valid information on whom such procedures are effective.

Thank you for sharing your views with the Department.

Sincerely,

GOOLOO S. WUNDERLICH, PH. D.,
Acting Director, Office of Policy Development and Planning.

ROSWELL PARK MEMORIAL INSTITUTE,
DEPARTMENT OF HEALTH, STATE OF NEW YORK,
Buffalo, N.Y., August 3, 1977.

GOOLOO S. WUNDERLICH, Ph. D.,
Acting Director, Office of Policy Development and Planning, Office of the Assistant Secretary for Health, Washington, D.C.

DEAR DR. WUNDERLICH: Your letter of July 22, 1977 is a perfect illustration of the Least Action Principle of Bureaucracy: Do as little as possible but try to sound as if you have done as much as possible. Secretary Califano asked for an evaluation of a specific proposal that would protect the American public against serious health hazards from unnecessary x-rays. It is the responsibility of your Office of Policy Development and Planning to make such an evaluation. Instead of doing your job and running a preliminary cost-benefit analysis of the proposal, you use the usual bureacratic ploys to reject the proposal. This is in line with the Least Action Principle. It saved you the effort required either to understand the public health hazard or this proposal for primary prevention of this hazard. As it happens, however, I spent 18 years as a health bureaucrat and know these ploys (which I've sometimes used myself).

Before getting to the ploys, let's look at the problem. We can indeed "agree that there is a major problem in unnecessary x-ray examination and, certainly, the present climate of malpractice and the availability of third-party reimbursement has contributed to the increased use of x-rays". Again, the Bureau of Radiological Health (BRH–FDA) estimates you cite—"the approximately 30–40 percent" of "270 million medical and dental" x-rays are "unnecessary with respect to the patient's clinical requirements"—are higher than the estimates in my June 17, 1977 testimony to Senator Stevenson's committee (which were for medical x-rays only). For the same reason, your estimate that the "cost of these unnecessary x-ray examinations is approximately $2 billion annually" was higher than the estimate in my testimony. However, your letter ignores a far more important cost than I emphasized in my testimony, the serious genetic damage to 100,000–500,000 Americans that is produced each year by this unnecessary x-ray. This genetic damage will eventually result in leukemia or other diseases in the person exposed or in the children of this person.

While we are in some agreement on the nature and scope of the problem of unnecessary x-rays, we are in complete disagreement on what the Office of the Assistant Secretary for Health should do about the problem. I proposed a simple and practical way to eliminate most of the unnecessary medical x-rays within a year or two and to save the taxpayers billions of dollars as a bonus. On the other hand, in accord with the Least Action Principle, your office is determined to do nothing about this serious public health problem. You "justify" your failure to carry out the mission of your office with the standard ploys and excuses for inaction.

One of these ploys is the "Insurmountable Obstacle" routine. When bureaucrats don't want to do the job for which they are being paid by the taxpayers they become expert at finding "insurmountable obstacles" where none exist. Thus the only reason offered for rejecting the proposal is: "It is extremely difficult to develop objective standards for determining the need for each kind of x-ray examination without impinging inappropriately on the physician's judgment." There are, indeed, difficult decisions (such as whether to give x-ray to a pregnant woman with possible rib fractures or other serious injuries) but the vast majority of unnecessary x-rays are given in situations where there is no serious medical problem and where objective standards are not "extremely difficult".

According to a federal survey of general practitioners, no more than 1 x-ray in 30 is given to patients with a very serious medical problem and only 1 in 3 to patients with a problem that is at all serious. Most of the x-rays (and the vast majority of unnecessary x-rays) are given to patients who have minor problems or have no symptoms at all. For the past decade, public health experts evaluating the use of x-rays on such patients (often under the heading "radiological surveillance" to distinguish this from x-rays given for some clear medical reason) have strongly recommended against such x-rays except in a few "marginal" situations. Our new findings on hazards have shifted the cost-benefit balance drastically and virtually eliminated these "marginal' cases. In short, the present cost-benefit balance (which your office should have taken the trouble to look into) is such that the delivery of x-rays can now be covered by the following explicit and objective standard: X-ray should not be given unless there is a clear medical reason to do so.

There will, of course, be circumstances with seemingly healthy patients where there will be a reason for x-ray (a suspicion of cancer from a pattern of minor complaints would be such a reason). The Certificate of Necessity allows the physician to state his reasons in such cases. The two physicians who must sign this certificate, the dotcor ordering the x-ray and the one delivering it. are not restricted in their medical judgment. The restriction is solely on third-party reimbursers and *not* on the physicians. These points should have been clear from my testimony to Senator Stevenson. If not, they could have been cleared up if you had been willing to make a telephone call to get the pertinent information for a real evaluation of the proposal.

The opposite of the "Insurmountable Obstacles" ploy is the "It's-Been-Done" ploy. You may claim that the BRH programs described in your letter will "significantly reduce" x-ray exposure but, as you ought to know, the facts are against you. Both the BRH estimates of the scope of the unnecessary x-ray problem and the BRH programs you mention have been around for a long time. The fact is that these programs have failed to make any dent in the problem. Indeed, from a planning standpoint it is just plain silly to expect that radiologists can be "reeducated" to voluntarily accept a drastic cut in their income. In claiming that failed programs can do the job, you are using the "It's-Been-Done" ploy to put down a proposal that actually can do the job.

Why should the Office of the Assistant Secretary of Health be so anxious to kill a proposal that would prevent unnecessary x-rays that are producing massive genetic damage to the American public and costing this public billions of dollars? The answer is the key phrase "impinging inappropriately on the physician's judgment." Since ordering millions of unnecessary x-rays is clearly bad judgment, why is it inappropriate to "impinge" on this judgment? The answer is simply that with the present federal health policies of kow-towing to the health industry, *any* effort to protect the public against iatrogenic disease is officially "inappropriate". An experienced health bureaucrat, I would translate your delicate phrasing into plain English as follows: Requiring a Certificate of Necessity would bring a horde of angry lobbyists from the physicians, hospitals, and insurers down on the HEW and Congress. Rather than to risk the displeasure of groups forming the "constituency" of the federal health agencies, it is "safer" to follow the Least Action Principle and "let the public be damned".

HEW's least action poliices may have been smart politics in the past, but times are changing. Your office has responsibilities for the regulation of the health industry. For a long time it was fashionable for regulatory agencies to be more concerned with protecting the interests of those that they regulated than the interests of the public. Except at HEW, this is going out of style. So when you are asked to evaluate a proposal which on one hand means some extra paperwork for the health industry and on the other hand would eliminate tens of millions of unnecessary x-rays, prevent genetic damage to hundreds of thousands of Americans, and save taxpayers billions of dollars, it might nowadays be "safer" for your office to take the trouble to run a proper cost-benefit analysis instead of rejecting the proposal out of hand for political reasons.

Let me say a word about the paperwork. Usually I'm against red tape but there are a few circumstances where red tape operates in the public interest and this is one of them. The doctors who order the unnecessary x-rays are almost always following the Least Action Principle. Rather than to take the extra time, effort, or thought to do a good physical exam, think about the patient's symptoms, or weigh the benefits and costs to the patient it is easier to order an unnecessary x-ray. Filling out a Certificate of Necessity is simple when there is a good medical reason for the x-ray so good practice isn't hampered. It is more trouble to fake a reason so physicians who are following the Least Action Principle would find it easier to forego the x-ray than to go to the extra trouble.

As I mentioned in my testimony, there should be light monitoring of the certificates by a computerized system. The system costs would be relatively small and the savings hundreds of times the costs. Third-party reimbursers (not MD's) who are experienced at red tape are the ones who would be directly involved with the monitor system and therefore it would be quite manageable. However, even without much monitoring, the little extra effort in filling out a Certificate of Necessity would drastically reduce the number of necessary medical x-rays.

Much more important than the savings of the money is the prevention of hundreds of thousands of cases of genetic disease that would otherwise result from the unnecessary x-ray, the cost that was completely ignored in your letter. An office responsible to the Assistant Secretary of Health for planning and policy should be aware that our studies and those of Mancuso, Stewart, and Kneale show the health hazards are much worse than what was predicted in the past (e.g., BEIR Report) by extrapolation from hazards at high doses of x-ray. Enclosed is a report on "Genetic Damage from Diagnostic X-ray" by Bross and Natarajan that appeared on May 30, 1977 in the Journal of the American Medical Association. As mentioned in my testimony, we have much additional information on the health costs of unnecessary x-ray that has not yet been published. These findings are based on a study of 13,000,000 humans exposed to ordinary diagnostic x-rays rather than 200 rats exposed to very high doses of saccharin. You cannot be expected to know about these major new findings. You can be expected to take the trouble to find out about them before rejecting a new public health proposal to deal with these health hazards.

The Least Action Principle is bad for the public wherever it operates but in the area of protection of the health and safety of the public it is unconscionable.

Very sincerely yours,

IRWIN D. J. BROSS, Ph. D.,
Director of Biostatistics.

P.S.—The statements made here represent the views of individuals in the Biostatistics Department and should not be construed as officially representing Roswell Park Memorial Institute for Cancer Research.

Senator STEVENSON. Our next witness is Dr. John Osepchuk of the Institute of Electrical and Electronics Engineers.

STATEMENT OF DR. JOHN OSEPCHUK, THE INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS, INC., COMMITTEE ON MAN AND RADIATION, RAYTHEON DIVISION, WALTHAM, MASS.

Dr. OSEPCHUK. I will try to abstract and highlight my written testimony.

Senator STEVENSON. Thank you, sir.

Your full statement will be entered in the record.

Dr. OSEPCHUK. Thank you.

Mr. Chairman, on behalf of the COMAR Committee of the IEEE, I thank you for the opportunity of appearing before you today to testify on the need for a realistic perspective in assessing the hazards of nonionizing radiation.

The Committee on Man and Radiation was established in 1972 by the Institute of Electrical and Electronic Engineers, which is the leading professional society in electrical engineering with about 160,000 members worldwide. The primary purpose of COMAR is to present factual information on the biological effects of nonionizing electromagnetic radiation to the general public, including legislators. Even in 1972 there was much false or misleading information on this subject in the mass media. Therefore, COMAR was charged in particular with the task of rebutting this misinformation by appropriate means.

The present membership of COMAR consists of 14 scientists and engineers involved in various ways with development and application of bioeffect research data or safety standards for man relative to nonionizing radiation. The committee roster is included as appendix A. The statements and material presented by COMAR generally represent the consensus of the committee, although individual efforts are encouraged when necessary for more timely and effective results.

Since 1972, COMAR has found a continuing need for its function as a source of factual information to the general public because the mass-media coverage of this subject has continued to exhibit serious misinformation and flagrant embellishments of the truth that tend to highly exaggerate the degree and nature of hazards of nonionizing radiation. It should be recognized that a failure of responsible groups and individuals to rebut this false picture could lead to serious harm in our society including:

(*a*) Deprivation or delay of beneficial applications of electromagnetic technology;

(*b*) Unnecessary fears of citizens and consumers of electricity;

(*c*) Depressed activity in technical industries;

(*d*) Additional costs to consumers; and

(*e*) Additional costs to citizens.

The dangers we speak about here are not imagined. Examples in each category can be cited. A particularly poignant example is worth citing. In 1974, a woman upon becoming pregnant became so fearful of possible birth defects because of some previous microwave diathermy applied to the back that she contemplated abortion as a solution. She was dissuaded from this action after receiving factual information from medical and physical scientists that dispelled her association of microwave "radiation" as a source of birth defects akin to nuclear radiation which she had gathered from the mass media.

A real danger is that our societal frame of mind could drift into a Luddite-like antitechnology posture despite our sophistication. In 1973 testimony before the Senate, I complained about the reliability of information in the field of nonionizing radiation and said that "some of this published information will someday be ranked with Wilhelm Reich's Orgone box' in a list of RF fantasies."

Despite much good research since then, there continues to be generated much misinformation in the category of "RF fantasies." COMAR has attempted to rebut this information and inject realistic perspective.

To achieve such a perspective a minimum of understanding of technical concepts is a necessary ingredient. COMAR has attempted to inject these concepts into public discussions, and I will now review them.

In figure 1 we show the electromagnetic spectrum and some of the principal uses and band designations. The spectrum of nonionizing radiation is essentially bounded on one side by 60 Hz, the frequency of household electricity, and on the other side by optical frequencies corresponding to infrared and visible light. In the wide spectrum between these limits lie most of the communication uses (including broadcasting, CB radio, and radar) and the noncommunication uses, or power applications, which utilize certain restricted ISM bands (industrial, scientific, and medical). The principal ISM bands are denoted by black bars.

Roughly speaking, the so-called microwave frequency range lies centered between the low and high ends of the nonionizing spectrum. Although the "microwave" designation is often somewhat arbitrarily defined, there is a rational definition which relates meaningfully to biological exposure hazards. It can be shown that for any size object with electrical properties similar to biological tissue, there is a frequency range roughly centered where free-space wavelength is of the order of the body dimensions for which penetration of electromagnetic field is greatest, maximum total absorption occurs, and peak internal absorption with likely "hot spots" occur. At very low frequencies the body acts like a conductor and shunts out the electric field. At very high frequencies the radiation behaves optically and is absorbed near the surface of the body. The existence of such a frequency range with unique properties of maximum penetration is schematically depicted in figure 2. This broad frequency range is denoted the microwave range and corresponds to the technical basis of alternative definitions where the size of apparatus or objects of interest determines where "microwave" properties occur.

Crudely speaking, we can state that there is a resonant frequency (or range of resonant frequencies) for each object that varies with size and shape. This principle was recognized years ago by the inventor of the microwave oven, Percy Spencer, when he stated that optimum deep heating of food occurred when the wavelength of the radiation is of the order of the food size.

Well, what does this mean? Consider a microwave (2450 MHz) power density of about 50 mW/cm^2 which is similar to the level of solar radiation at the Earth. A fruit fly flying around in this radiation will be unbothered by this. A mouse will expire in several minutes. An elephant (which would require a very expensive experiment) I think will react much like he would under full sunlight. Remember, the same frequency, and we have entirely different reactions.

One cannot talk about these effects without injecting this very fundamental engineering consideration which has biological ramifications.

In figure 2, I sketch this concept of a resonance region. In figures 3 and 4, I include some data from recent technical literature which supports this picture.

Now, let's turn to the question of standards, exposure, and emissions. In figure 5 we list some of the principal exposure standards which specify what the power density and what the duration of exposure should be to a person without getting into any trouble. On the other hand, emission standards talk about what the equipment should give off—the maximum close to, or at some point near the equipment. They (exposure and emission standards) are not the same thing, even though they use the same numbers. First, let's look at exposure. The U.S. standard is well known—10 mW/cm^2 for unlimited duration.

The Soviet standard is less understood. I might bring in a couple of points here. The U.S. standard has a safety factor of at least 10. It protects against potentially irreversible damage. The Soviet standard has a safety factor of 100 and protects against reversible functional disturbances believed to occur per chronic exposure. And I quote from a recent book to give added prespective to this standard. In one of their books they point out that "exposure to a field with an intensity of about a few or even tens of microwatts per square centimeter cannot be regarded as in any way dangerous".

One clear lesson to be drawn from this review is that the exposure limit is not a boundary between hazard and safety. And the Soviets agree with us that there are real thresholds for damage and there is no truly cumulative effect such as postulated with ionizing radiation.

There is no evidence that truly long exposure of duration of many days is in any way harmful. Such exposure can occur from broadcasting sources, for example.

Now, I won't go through all of the background about why the emission standard of the microwave oven is very, very conservative. After much education, I think it has gotten through, but we hope to nail the lid on this subject once and for all by pointing out that the Russians and the Poles and the Czechs have adopted essentially the same emission standard. I quote from Dr. Czerski, who says that this emission standard in the United States and the U.S.S.R. exposure standard do conform exactly, and he would be only too happy to import such ovens into his country. And there is a proposed emission standard that will be promulgated by the Ministry of Public Health of the U.S.S.R. They are making microwave ovens and they hope to be manufacturing them in production very soon.

And I won't go into the details, but it's essentially equivalent both in their view and my view to the U.S. standard. Whatever the debate about exposure standards, the oven standard is compatible with any other exposure standard.

Let's apply some of these facts to public debates. In 1973 the Consumer's Unions called for zero leakage. Zero leakage is really absurd. But it took a lot of time to explain that microwaves at any low level are not dangerous. The same kind of fear apparently occurs when people try to stop construction of microwave relay towers.

People fear that microwave radiation at any low level could be potentially dangerous. This is science fiction. If we were to say that, you might as well shut down broadcasting and everything that emits anything. This type of irrationalism has spread. Unfortunately, the Moscow Embassy incident has created great problems in this regard.

Let me read my prepared statement on this: In the last 2 years considerable publicity and speculation has occurred in the news media concerning the microwave irradiation of the U.S. Embassy in Moscow. COMAR has requested the U.S. State Department to officially release sufficient technical details on the radiation to permit convincing assessment by professional groups of the degree of hazard, if any. Unfortunately, the State Department has declined to do this beyond confirming that the maximum radiation level is of the order of 1μ W/cm^2 except for a brief period in 1976 when it reached 18μ W/cm^2.

These levels apparently are confined to certain areas of the building and over most of the building the levels are far below hazard levels implied in the viewpoints underlying either U.S. or U.S.S.R. exposure standards and are comparable to ambient levels that exist from broadcasting sources in modern society.

Thus there appears no basis for the fearful speculations in the press and the official denial by the State Department of a relation of the radiation to personnel health problems appears valid. COMAR believes, however, that a more forthright description of the radiation by the State Department would serve to produce a more satisfying rebuttal of the speculative fears.

COMAR has supported HEW, the medical profession, and industry in opposing a series of proposals in individual cities and States for required warning signs around microwave ovens aimed to protect pacemaker wearers against potential interference.

COMAR has commented to the Bureau of Radiological Health and the Technical Electronic Products Radiation Safety Standards Committee (advisory to the HEW Secretary) on various proposed standards. In particular, it has opposed the requirement of warning labels on microwave ovens.

The requirement was promulgated but with the possibility of exemption provided.

COMAR in the last 2 years has opposed a proposed emission standard on microwave diathermy applicators because it is overly conservative, would cause the one U.S. manufacturer of such diathermy to cease production of such devices and would discourage extension of such diathermy to new objectives such as cancer therapy.

COMAR members have provided information to a radio broadcaster whose transmitter was alleged to be a potential "radiation" hazard by an abutter who planned to develop the land near the transmitter.

COMAR has responded to many articles in the press and programs in the broadcast media which have distorted the nature of nonionizing radiation hazards.

Most recently, COMAR has responded to the articles by Paul Brodeur on "microwaves" by letter and by issuing for public release a detailed critique and rebuttal of Brodeur. The latter had implied that the military, government, industry, and the scientific community were engaged in covering up serious potential hazards of nonionizing radiation and that serious potential hazards to the general population existed from such radiation. COMAR found Brodeur's thesis unfounded and the publication of his articles a disservice to the general public.

COMAR has consistently supported an effective program of research on the bioeffects of nonionizing radiation and has sought to inject professional society skills into the planning and review of such research.

COMAR, it must be repeated, strongly supports programs of research on bioeffects of nonionizing radiation—but not for the wrong reasons which are suggested in the press. There is no crisis—no imminent health hazard from low-level NIR. Potential payoff to society may not be predictable if it is truly good science but one can speculate at least that such research will:

(a) Permit more accurate safety standards.

(b) Permit the development of new medical applications.

(c) Seek out potential biological applications.

(d) Create useful spinoff knowledge of use to the industrial heating and microwave oven businesses.

As far as our advice for research, figure 7 shows that most research is with wavelengths of around 10 cm. and animals of similar size. Thus one gets interesting resonance effects. But we're interested in man. So I make some suggestions here about doing more work on the frequency dependence of effects and on scaling so that one can start to relate this to man. More professional societies should be involved. More research should be done on millimeter waves, cancer therapy, and general heating.

However, lastly, there is a real problem of public education. This started with the electric lamp about 100 years ago, and it recurs.

In the first 50 years of this century there were many spectacular claims about what good could be done with nonionizing radiation for medicine. This is the reverse of the present situation. This led to exploitation by some M.D.'s and industry which was later condemned by the medical profession.

Now, since World War II, all kinds of fables have arisen about microwaves and the review of these fables in an entertaining treatment was made by Dr. Justesen. This is in appendix B. An example of misconceptions is shown in the following example. Years ago, a young intelligent M.D. heard that I was involved in Senate Hearings on microwave oven radiation hazards. And he asked me, "Are those gamma rays or beta rays?" If an M.D. could have that much confusion from what he reads in the press, I suggest that we have a real problem with the general public, as well.

It is apparent that there is a need for better public education on the nature of electromagnetic energy, its benefits and potential hazards even among sophisticated elements of our society. Topics that need to be clarified include:

(a) the fact that electromagnetic energy associated with the spectrum from ordinary elecricity to visible light is nonionizing and is not equivalent to the "radiation" associated with X-rays or nuclear systems which display potential for cumulative and more insidious effects;

(b) the fact that nonionizing electromagnetic energy has been in use in many areas of modern society for many years without validation of serious human injury due to radiation effects;

(c) a better understanding of what modern bioeffect research is doing and what it means—for example, that effects, like sensation, do not necessarily imply hazard. The common experience of static shock after walking on a rug is an example of significant localized electrical energy;

(d) the beneficial uses of electromagnetic energy ranging from household electricity, broadcasting to medical applications;

(e) the fact that sufficient understanding of the effects of electromagnetic energy to protect against known thermal hazards has been available for years. The key papers of Mumford, a member of this committee, and Kalant in the early 1960's provided an authentic engineering and medical assessment of potential hazards. Since then the works of leading researchers like Schwan, Michaelson, and Guy have improved and extended this understanding toward a more exact quantitative formulation. Nevertheless, the conclusion of Kalant appears as valid today as it was earlier—namely, "practical protection of human beings against damage due to excessive microwave energy appears to require chiefly the application of commonsense and sound engineering directed against known dangers, rather than a search for new and as yet unrecognized dangers."

It is helpful at this point to quote a principal conclusion from the paper by Justesen, "The assumption of hazardous nonthermal effects at low densities of radiation, which are suspected by some but are as yet unsubstantiated by anyone, is a fabrication from the wholecloth of fear. This fear, which feeds on the absence of verified or verifiable evidence, is hampering basic studies and may thereby restrict medical development and application of radio-frequency radiations."

It is the aim of COMAR to help achieve rational perspective in our society with regard to potential hazard of nonionizing radiation. It would be very desirable if efforts toward public education could be expanded and improved. It should be possible for government agencies to sponsor educational material, not only for the printed media, but also radio and television.

Thank you.

Senator STEVENSON. Thank you, sir. You mentioned the microwave diathermy treatments. How do you know whether there have been any deleterious effects from that treatment?

Dr. OSEPCHUK. I don't know the exact degree of the monitoring programs. But I know some specific programs where doctors applied treatments to the eye. Dr. Clarke, for many years, in Louisiana, followed many patients after treatments of the eye and never saw a cataract in those patients. Similar results, have been reported by Dr. Merriam in New York.

Professor Lehman of the University of Washington has stated for the 1973 hearings that in his view, and the view of his profession, that there has been no deleterious effect to patients undergoing this modality when prescribed according to professional conditions.

And the details behind this I cannot describe at this time. But Professor Lehman and the profession state that this is the case.

Senator STEVENSON. Well, I am not sure their conclusions are based on any systematic monitoring.

Dr. OSEPCHUK. When you have several million patients, and there are found no really serious problems there is a real practical support for the conclusion.

Senator STEVENSON. But you said it had not caused cataracts. You quoted the first doctor as saying that his therapeutic treatment had not caused cataracts. What else didn't it cause?

Dr. OSEPCHUK. Well, I don't know. But in that particular case, there was particular concern about cataracts. So they made a special monitoring of that problem.

Senator STEVENSON. In his testimony before the committee yesterday, Dr. Schiff of George Washington University said one of the more disquieting findings demonstrated rather conclusively by Dr. Carpenter is that the effects of microwaves may be cumulative. Now, you have said the Soviets agree that there are no truly cumulative effects such as that postulated with ionizing radiation. How do you explain this discrepancy?

Dr. OSEPCHUK. I anticipated that. Dr. Schiff gave a good review, but I am afraid he is wrong there. And with your permission, if I hold up figure 5, which is in the text, and I won't belabor the subject, but the U.S.S.R. standard shows a stepwise decrease in level to $10\mu W/cm^2$. But it stops at this point. If you go on in exposure to continuous periods of days, weeks, or months, the level does not keep going down but remains at $10\mu W/cm^2$.

Dose is a multiplication of exposure rates and time. So by definition, if you look at the U.S.S.R. exposure standard, it does not imply cumulative figures out to very long time periods.

With respect to Dr. Carpenter, I am afraid that there is a distortion of what Dr. Carpenter said and has found. Dr. Carpenter's experiments were with rabbits, with several hours of exposure, at levels of 150–180 mW/cm^2 and limited exposure area. If he exposed the whole animal it runs away or gets killed—you limit the exposure only to the eye, then you can produce cataracts in the eye.

Now, his so-called cumulative effect—and this is kind of an academic debate, as far as I am concerned—occurs in the range of 75 and 150 mW/cm^2. One single exposure may not cause a cataract, but maybe five or six will. So something happens there. Let's ask the next question. Let's go down to 50, 40, 30, 10. . . . At those levels nothing happens.

Dr. Carpenter conducted chronic exposures of rabbits at 10 mW/cm^2 for many months. Dr. Guy did the same thing at the University of Washington for many months. If there were a cumulative effect, it should show up at that level and not just at the near-threshold level. There were no cataracts. The data is so uninteresting that they have stopped looking into it. So, I think that research should close the matter.

I am afraid the term cumulative effect has been misapplied. It certainly is confusing to the layman because that usually means it is something like ionizing radiation, but it is not.

Senator STEVENSON. You say, "COMAR pointed out that fears of microwaves at any level were irrational." Is that really what you are suggesting?

Dr. OSEPCHUK. Yes.

Senator STEVENSON. Any level?

Dr. OSEPCHUK. Yes. What I am trying to say is this: One should obviously be afraid, if there is 100 kilowatts of energy around that could be dumped into you. That is a very, very high level. What I am saying is that if one is afraid of microwaves, no matter how low the level is, then that is irrational. One's fears should depend upon how strong the force on the available power is.

Let me make an analogy with the electric lamp. We live with 100-watt lamps. We are safe. If I put one next to my eye, I think there will be a problem in a little while. We instinctively keep a safe distance so it is acceptable. On the other hand if I had a 1-watt bulb up to my eye, nothing will happen.

And in the same way, if we are dealing with a small amount of RF energy, our own history and commonsense implies that there is little, if any hazard. There is certainly nothing to worry about because it exists, period, whether you do anything about it or not. Whereas, if there is a 100 kilowatt RF source in a plant with potential exposure, you are going to be very careful because 100 kilowatts can do something to you very quickly.

Senator STEVENSON. You indicated that more research is needed to be done on certain bioeffects. Could you explain what research needs to be done?

Dr. OSEPCHUK. I am referring to the research programs that are going on right now which I think, by and large, are well run by the agencies—OTP and particularly the military who support most of the research, I think. They shouldn't be judged upon the time factor, but on how much money has been spent. But the time has come for all of the research organizations to stop just doing animal experiments without addressing more frontally what does this mean for man.

I indicated some need for work on physical scaling. And there are biological aspects that can be worked on in terms of addressing it to man. What can one do, for example? You have this business of scaling and frequency dependence which can be verified by experiments, with small animals over a wide frequency range. Then one should do experiments on bigger animals. In this way you build up the confidence that one knows how to extrapolate from an animal, to a bigger animal, and finally to man. I can guess that the most dramatic biological effects will occur in a limited frequency area, because that is where the physical resonance exists. But we can't really make quantitative statements on scaling right now.

Senator STEVENSON. EPA indicated yesterday that their attitudes toward nonionizing radiation has changed. They are more concerned now than they were before they began their recent studies. But those studies won't produce a report on the scope of the problem before March of next year.

Are you familiar with those studies?

Dr. OSEPCHUK. I think so. I think I know what they are referring to. All of these experiments were with small rodents, rats and mice in a resonance—frequency range, at levels of the order of a few milliwatts to 20 milliwatts per centimeter squared.

Senator STEVENSON. You are not concerned about a new environment in which man is exposed to more and more microwaves, more and more high voltage lines, more lasers, and more powerful magnets and all the rest?

Dr. OSEPCHUK. I am concerned. But I am not worried. I think things are under control.

Senator STEVENSON. You mention this research. History repeats itself. We don't want to repeat the experience of chemical pollution of our environment. Perhaps the research will take 30 or 40 years to come up with conclusions. And perhaps by then, it will be too late.

Dr. OSEPCHUK. We are not starting from zero. We already have some safety standards. We already know—regardless of safety standards, how one can guard against hazards. But some of the things that you mentioned are out of perspective. You mentioned high voltage lines, 60 hertz. I can show you excerpts from the press where they talk about the "radiation" from these things. What radiation are they talking about? Now people don't realize that if we are talking about the field strengths at 60 hertz in nearby homes not directly under the powerline, those field strengths of high-voltage line "radiation" as some moderate distance from the high voltage line, at that point, are less than the field strengths that one gets when one puts a hair dryer on one's head or other applicances that are close by.

So what we are starting to do is indict these household electricity frequencies. And there is another interesting and related area. Broadcasting is one area of technology where we are all irradiated directly by somebody else, not by our own choice, because you would not get a signal on our TV set, if you were not being irradiated, whether you want to watch the set or not.

Now, I am not arguing for any campaign against this or that. But I want to put all things in perspective. I still want research. We still want research, but there is no crisis.

Senator STEVENSON. I don't think we are suggesting that there is a crisis now.

Dr. OSEPCHUK. Well, the press does occasionally. And unfortunately, people believe the press.

Senator STEVENSON. We all know that they do tend to exaggerate things sometimes.

Dr. OSEPCHUK. Some people believe that one should research things completely before they are used. But remember, there is a lot of potential benefit, like Dr. Justesen says. Some of these things will be delayed if people have an irrational view of this electrical energy that is called radiation.

And in fact this technology can help save energy because of its efficiency in heating or it can become useful in cancer therapy. If it is looked upon as another source of energy and not "radiation," with all types of mysterious connotations, I think it could be potentially useful.

Senator STEVENSON. Do you think current research budgets are adequate?

Dr. OSEPCHUK. Well, being a researcher myself—we always look through different colored glasses—I am sure the budgets are always too low. But outside of that prejudice, I would say that it is being fairly well planned and managed by the existing agencies.

I think, particularly, the military agencies have done far more than their share and have been unnecessarily maligned considering the fact that they have supported this research for so many years. And they don't control the researchers. Most researchers I know have been supported by the military. For better or worse, there is good work being done.

Senator STEVENSON. Thank you, sir.

Dr. OSEPCHUK. You are welcome.

Senator STEVENSON. If Senator Schmitt or others have questions, we will take the liberty of following up.

Thank you.

[The statement follows:]

STATEMENT OF DR. JOHN M. OSEPCHUK*

Mr. Chairman and members of the Committee, on behalf of the COMAR Committee of the IEEE, I thank you for the opportunity of appearing before you today to testify on the need for a realistic perspective in assessing the hazards of non-ionizing radiation.

The Committee on Man and Radiation (COMAR) was established in 1972 by the Institute of Electrical and Electronic Engineers (IEEE) which is the leading professional society in electrical engineering with about 160,000 members worldwide. The primary purpose of COMAR is to present factual information on the biological effects of nonionizing electromagnetic radiation to the general public, including legislators. Even in 1972 there was much false or misleading information on this subject in the mass media.[1] Therefore COMAR was charged in particular with the task of rebutting this misinformation by appropriate means.

The present membership of COMAR consists of fourteen scientists and engineers involved in various ways with development and application of bioeffect research data or safety standards for man relative to non-ionizing radiation. Included as members are two representatives of the medical and life sciences. In addition, the committee is in close contact with the entire research community on bioeffects of nonionizing electromagnetic radiation. The Committee roster is included as Appendix A. The statements and material presented by COMAR generally represent the consensus of the committee although individual efforts are encouraged when necessary for more timely and effective results.

Since 1972 COMAR has found a continuing need for its function as a source of factual information to the general public because the mass-media coverage of this subject has continued to exhibit serious misinformation and flagrant embellishments of the truth that tend to highly exaggerate the degree and nature of hazards of nonionizing radiation. It should be recognized that a failure of responsible groups and individuals to rebut this false picture could lead to serious harm in our society including:

(*a*) Deprivation or delay of beneficial applications of electromagnetic technology—whether civilian communications devices or new cancer therapy devices;

(*b*) Unnecessary fears of citizens and consumers of electricity in general and electronic products specifically;

(*c*) Depressed activity in technical industries with loss of employment on all levels;

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*Raytheon Research Division, 28 Seyon St., Waltham, MA 02154.

[1] See for example: Paul E. Tyler, "Overview of Electromagnetic Radiation Research: Past, Present, and Future." pp. 6–14, Proceedings of a Symposium on "Biologic Effects of Nonionizing Radiation," held on February 12–15, 1974; published in the Annals of the New York Academy of Sciences, Vol. 247 (Feb. 28, 1975).

(*d*) Additional costs to consumers reflecting costs of dealing with unnecessarily complicated and overly conservative government regulations;

(*e*) Additional costs to citizens resulting from ill-based litigations stimulated by irrational fears;

(*f*) Additional costs to citizens of increased governmental activity of an unproductive nature.

The dangers we speak about here are not imagined. Examples in each category can be cited. A particularly poignant example is worth citing. In 1974 a woman upon becoming pregnant became so fearful of possible birth defects because of some previous microwave diathermy applied to the back that she contemplated abortion as a solution. She was dissuaded from this action after receiving factual information from medical and physical scientists that dispelled her association of microwave "radiation" as a source of birth defects akin to nuclear radiation which she had gathered from the mass media.

This example is probably not an isolated case in our technological society. Recently a study in Science[2] reported on unnecessary abortions that were triggered by scare stories based on premature results associated with possible hazards of some spray adhesive that were later found to be invalid.

A real danger is that our societal frame of mind could drift into a Luddite-like antitechnology posture despite our sophistication. In 1973 testimony[3] before the Senate I complained about the reliability of information in the field of nonionizing radiation and said that "some of this published information will someday be ranked with Wilhelm Reich's 'Orgone box' in a list of RF fantasies". Despite much good research since then, there continues to be generated much misinformation in the category of "RF fantasies". COMAR has attempted to rebut this information and inject realistic perspective. (The activities of COMAR have reflected considerable effort on the part of past chairman H. Mark Grove and present chairman, Dr. H. Allen Ecker.)

To achieve such a perspective a minimum of understanding of technical concepts is a necessary ingredient. COMAR has attempted to inject these concepts into public discussions and I will now review them.

In Fig. 1 we show the electromagnetic spectrum and some of the principal uses and band designations. The spectrum of nonionizing radiation is essentially bounded on one side by 60 Hz, the frequency of household electricity, and on the other side by optical frequencies corresponding to infrared and visible light. In the wide spectrum between these limits lie most of the communication uses (including broadcasting, CB radio and radar) and the noncommunication uses, or power applications, which utilize certain restricted ISM bands (Industrial, Scientific, and Medical). The principal ISM bands are denoted by black bars.

Roughly speaking, the so-called microwave frequency range lies centered between the low and high ends of the nonionizing spectrum. Although the "microwave" designation is often somewhat arbitrarily defined, there is a rational definition which relates meaningfully to biological exposure hazards. It can be shown that for any size object with electrical properties similar to biological tissue, there is a frequency range roughly centered where free-space wavelength is of the order of the body dimensions for which penetration of electromagnetic field is greatest, maximum total absorption occurs and peak internal absorption with likely "hot spots" occur. At very low frequencies the body acts like a conductor and shunts out the electric field. At very high frequencies the radiation behaves optically and is absorbed near the surface of the body. The existence of such a frequency range with unique properties of maximum penetration is schematically depicted in Fig. 2. This broad frequency range is denoted the microwave range and corresponds ot the technical basis of alternative definitions where the size of apparatus or objects of interest determines where "microwave" properties occur. For most biological and other objects of interest to man, including man himself and other animals, the microwave range is meaningfully assigned to 10 MHz to 100 MHz, the frequency range covered by the ANSI C95.1 exposure standard.[4]

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[2] E. B. Hook and K. M. Healy, "Consequences of a Nationwide Ban on Spray Adhesives Alleged to be Human Teratogens and Mutagens," Science 191, pp. 566–567 (1976).

[3] Hearings before the Committee on Commerce, United States Senate on Public Law 90–602, March 8–12, 1973, Government Publication No. 93–24, pp. 120–121.

[4] American National Standards Institute, ANSI Standard C95.1–1966 (Revised 1974), "Safety Level of Electromagnetic Radiation with Respect to Personnel," New York (1974).

Crudely speaking, we can state that there is a resonant frequency (or range of reasonant frequencies) for each object that varies with size and shape. This principle was recognized years ago by the inventor of the microwave oven, Percy Spencer, when he stated[5] that optimum deep heating of food occurred when the wavelength of the radiation is of the order of the food size. One can expect therefore, that maximum deep heat for a fruitfly occurs over 10 GHz—hamburger at ~2.45 GHZ—turkey at ~915 MHz—and man at ~100 MHz.

In fact, recent technical studies have yielded a more quantitative picture of the nature of the electromagnetic resonance of the human body. In Fig. 3 we show theoretical data for a human compared to experimental verification using scaled phantom models, taken from the work of O. P. Ghandi.[6] For the polarization indicated a significant absorption peak is predicted for the frequency range of 30–300 MHz depending on body size, at which frequency local internal hot spots are most likely. Similar work at the University of Utah has resulted in a "Dosimetry Handbook"[7] which suggests frequency dependence of absorption in man and animals based on simple theoretical models. The two examples in Fig. 4 show curves for man and a small rat, respectively. Again, even though there is some question on the accuracy of them, the gross features of body absorption are clear and confirm Percy Spencer's understanding of microwave heating principles. Frequencies above 1 GHz are most effective in deep heating of a mouse or a hamburger but the most effective frequencies for heating the whole of man are at the VHF range—those of FM and TV broadcasting.

In fact, the microwave-oven frequency of 2.45 GHz, although used for years in diathermy, has been determined[8] in recent years to be inferior to UHF frequencies for effective diathermy because of limited penetration at 2.45 GHz.

This description of how absorption of electromagnetic energy varies with body size, shape and frequency is important in assessing the relative hazards of different frequencies and especially important because it clearly indicates the need for some scaling process in relating the results of animal experiments to man.

Now we turn to a review of existing safety standards—both exposure and emission—so that a valid interpretation of these standards can be made in assessing risk in real-world situations which COMAR has dealt with.

An exposure standard applies to people—it specifies the maximum exposure (whole body) that personnel should subject themselves to. An emission standard applies to equipment and specifies the maximum permitted level of leakage radiation at specified points, usually close to the equipment. The two types of standards should not be confused because they are different concepts and not directly comparable.

Exposure is described by incident or ambient average power density and the continuous duration of such exposure to such power density. In Fig. 5 are shown the principal U.S. exposure standards and the U.S.S.R. exposure standard for microwaves. Both U.S. and U.S.S.R. standards are relaxed below a "microwave" range of frequency. The U.S. standard protects against thermal damage with a safety factor of at least ten. This is plausible since millions of microwave diathermy treatments, partial body, have been given to patients over the last twenty-five years with exposures indicated in Fig. 5 without deleterious effect.[9]

The Soviet microwave exposure standard also depicted in Fig. 5 shows a great difference to U.S. exposure standards for long duration, i.e., a 1000 to 1 ratio in permissible power density. A detailed review shows, however, that the overall differences are not as great as at first sight. First of all, the Soviet standard is intended to protect against reversible functional disturbances believed to occur for chronic exposure to levels above 1 mW/cm^2 whereas the U.S. standard protects against possibly irreversible tissue damage. Secondly, the Soviet and U.S. exposure standards come closer to agreement for short exposure duration.

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[5] P. L. Spencer, "Method of Treating Foodstuffs," U.S. Patent No. 2,495,429, Jan. 24, 1950 (filed Oct. 8, 1945).

[6] O. P. Gandhi. "Polarization and Frequency Effects on Whole Animal Absorption of RF Energy." Proc. IEEE 62, pp. 1171–1175 (Aug. 1974).

[7] C. C. Johnson, C. H. Durney, P. W. Barber. H. Massoudi, S. J. Allen, and J. C. Mitchell. "Radio Frequency Radiation Dosimetry Handbook", Report SAM–TR–76–35, Department of Bioengineering, University of Utah, September 1976; Prepared for USAF School of Aerospace Medicine

[8] A. W. Guy, J. F. Lehmann, and J. B. Stonebridge. "Therapeutic Applications of Electromagnetic Power," Proc. IEEE 62, pp. 55–75 (Jan. 1974).

[9] See Ref. 3, Letter from Prof. Justus F. Lehmann, pp. 462–463.

Thirdly, the Soviets imply the use of a safety factor greater than ten, viz: In one book,[10] after pointing out that functional disturbances occur at levels above 1 mW/cm^2 and exposure times longer than one hour it is stated (pp. 200–201 of NASA translation). "On the basis of this figure, one-tenth of the radiant intensity, i.e., 0.1 mW/cm^2, was recommended as the safe level for exposure throughout the working day (rounded off to 10 hours). For a tenfold hygenic safety margin, arrived at in view of the varying ages, individual sensitivities, etc., a still lower (by a factor of 10) intensity, i.e., 0.01 mw/cm^2) (10 μW/cm^2) has been recommended as the maximum permissible level".

In a more recent Soviet book[11] on page 317 it is stated: "The data from biophysical and medical investigations which are now available make it possible to conclude that the principal pathological changes arise during continuous prolonged irradiation by a field with an intensity 1. . . . 10 mW/cm^2 or more. . . . Accordingly, exposure to a field with an intensity of about a few or even tens of microwatts per square centimeter cannot be regarded as in any way dangerous".

One clear lesson to be drawn from this review is that the exposure limit in a safety standard is not a boundary between hazard and safety, the more so the greater the safety factor employed. Furthermore, the Soviets agree that there are real thresholds for damage and no truly cumulative effect such is postulated with ionizing radiation. There is no evidence even in the Soviet view that truly long-term exposure durations of many days of ambient levels of a few microwatts/cm^2 is in any way harmful. Such ambient levels can exist in modern society due to many sources, with broadcasting a prime source.

When we review existing emission standards we find a high degree of conservatism such that they are compatible with any exposure standards in the world. The principal emission standard in the U.S. is that applicable to microwave ovens.[13] It has been known for years that there is a high degree of safety associated with this standard such that a committee of the American Medical Association correctly associated[13] a safety factor of 10,000 by comparison with damage thresholds accepted by U.S. scientists. The conservatism of the U.S. microwave oven emission standard stems from the fact that it specifies the power density level close to the oven and not in a person operating the oven. Because the power density drops off roughly as the inverse square of distance from a source, levels of likely exposure are far lower than the emission values. In Fig. 6 we depict this inverse-square decrease of power density with distance. The U.S. microwave oven emission standard specifies a maximium of 1 m/W/cm^2 at 5 cm (2 inches) from the oven's external surface when new and 5 mW/cm^2 thereafter. These emission levels correspond to the order of one watt radiated and we can see from Fig. 6 that exposure levels below Soviet limits for 20 minutes, 2 hours and 8 hours are quickly reached a few feet from the oven. Studies[14] of likely operator locations have shown that even if the oven leaked at its regulatory limit of 5 mW/cm^2 at 5 cm, that likely exposure levels are well below U.S.S.R. exposure limits. This result is depicted in Fig. 5. The fact that most ovens leak far below this limit (e.g., 0.1 mW/cm^2) means that likely exposure near ovens meeting HEW regulations is trivial.

Some people such as Consumers Union[15] have confused emission and exposure and assumed that microwave ovens are not compatible with USSR exposure standards. Since 1969, however, evidence has accumulated that health authorities in Eastern Europe find the U.S. oven emission standard is fully compatible with their exposure standard. This evidence began in 1969 when Dr. K. Marha described[16] an emission standard for oven workers in Czechoslovakia essentially compatible with the U.S. emission standard. In recent years Dr. P. Czerski of Poland, one of the leading researchers in Eastern Europe, has stated this equivalence on many occasions. For example, in 1974, Dr. Czerski said":[17] "equipment performance standards in the U.S.A. . . . for microwave ovens and the U.S.S.R personnel exposure standards do confrom exactly and we would be only too happy to import any such ovens into Poland"

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[10] I. R. Petrov, editor, "Influence of Microwave Radiation on the Organism of Man and Animals". Academy of Medical Sciences of the U.S.S.R., Meditsina Press, Leningrad, 1970, pp. 200–201 of NASA translation.

[11] B. A. Minin, "Microwaves and Human Safety". 1974. Moscow, JPRS–65506–2, page 317.

[12] U.S. Dept. of HEW, FDA, Bureau of Radiological Health, "Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968", paragraph 1030.10 Microwave Ovens, pp. 36–37, PHEW Publication No. (FDA) 75–8003 (July. 1974).

[13] AMA Committee on Occupational Toxicology, Editorial, "Microwave Ovens," J. Amer. Med. Assoc. 215, No. 10, pp. 1661–1662, (March 8, 1971).

[14] J. M. Osepchuk, R. A. Foerstner, and D. R. McConnell, "Computation of Personnel Exposure in Microwave Leakage Fields and Comparison with Personnel Exposure Standards," Digest of the 1973 Microwave Power Symposium, Int. Microwave Power Institute, Edmonton, Alberta, Canada.

[15] Consumers Union, "Microwave Oven is not Recommended," Consumer Reports Magazine (April 1973).

This conclusion is repeated in a recent book[18] co-authored by Dr. Czerski. Lastly, it has been learned by personal communication[19] with Soviet scientists that microwave ovens will be manufactured in the USSR and that an emission standard has been recommended by a technical committee of the Ministry of Public Health. This standard specifies a maximum emission limit of 10 μW/cm^2, measured 50 cm in front of the door of the oven. By invoking the inverse-square law one can see that this is equivalent to the U.S. limit of 1 mW/cm^2 at 5 cm. This equivalence is accepted by the Soviet scientists.

The overall conclusion to be drawn from this review of microwave oven emission standards is that the U.S. emission standard is accepted world-wide. Thus, even though there is certainly current valid debate over exposure standards this debate does not affect whatsoever the question of microwave oven safety. The U.S. oven emission standard is considered adequate by the responsible scientists in all countries including those of Eastern Europe.

Having fixed in our minds some of the basic principles about microwave exposure and safety standards, let us review some of COMAR's activities in recent years to show how much of the public controversy about "microwaves" is irrational and can be dispelled by a knowledge of basic facts on the subject.

During its five-year existence COMAR has found many situations where misinformation was prominent in public discussions about hazards of non-ionizing radiation and in which COMAR has attempted to inject factual information and a realistic perspective.

In 1973 Consumer's Union questioned the adequacy of the HEW oven emission standard and called for "zero leakage". COMAR responded with letters to Consumer's Union and Senator Tunney and issued a press release. It was pointed out that CU had confused exposure and emission standards and that their goal of "zero leakage" was unnecessary, impractical and irrelevant in view of greater and more continuous exposure of the general population to finite levels of non-ionizing radiation.

Objectives similar to those of CU seemed to underlie the opposition of the Environmental Commission and individual citizens of Mahwah, New Jersey to a proposed microwave relay tower. COMAR pointed out that ground levels of radiation from the tower would be several orders of magnitude below even the USSR exposure standard, that thousands of such towers already exist without any evidence of radiation hazard, and that the fears of "microwaves" at any level were irrational. After a lengthy delay of two years and several hearings the New Jersey State Utilities Board finally approved construction of the tower.

In the last two years considerable publicity and speculation has occurred in the news media concerning the microwave irradiation of the U.S. Embassy in Moscow. COMAR has requested the U.S. State Department to officially release sufficient technical details on the radiation to permit convincing assessment by professional groups of the degree of hazard, if any. Unfortunately, the State Department has declined to do this beyond confirming that the maximum radiation level is of the order of 1 μW/cm^2 except for a brief period in 1976 when it reached 18 μW/cm^2. These levels apparently are confined to certain areas of the building and over most of the building the levels are unmeasurable with conventional hazard survey instruments. Such radiation levels are far below hazard levels implied in the viewpoints underlying either U.S. or USSR exposure standards and are comparable to ambient levels that exist from broadcasting sources in modern society.[20]

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[16] K. Marha, "Maximum Admissable Values of HF and UHF Electromagnetic Radiation at Work Places in Czechoslovakia," Proceedings of the Symposium on "Biological Effects and Health Implications of Microwaves," HEW Document BRH/DBE 70.2 (1970), p. 194.

[17] S. Michaelson et al., editors, *Fundamental and Applied Aspects of Nonionizing Radiation*, p. 432, Plenum Press, N.Y. (1975).

[18] S. Baranski and P. Czerski, *Biological Effects of Microwaves*, p. 183 and p. 186, Dowden, Hutchinson, and Ross, Inc., Stroudsburg, Pa. (1977).

[19] Personal Communication of Author with Dr. J. D. Dumansky and Dr. Los at the 1977 IMPI Symposium on Microwave Power, Minneapolis, Minn. (May 27, 1977).

Thus there appears no basis for the fearful speculations in the press and the official denial by the State Department of a relation of the radiation to personnel health problems appears valid. COMAR believes, however, that a more forthright description of the radiation by the State Department would serve to produce a more satisfying rebuttal of the speculative fears.

COMAR has supported HEW, the medical profession, and industry in opposing a series of proposals in individual cities and states for required warning signs around microwave ovens aimed to protect pacemaker wearers against potential interference. COMAR has helped to point out that the potential for interference is a pacemaker susceptibility problem rather than a radiation hazard, is essentially nil for modern microwave ovens, is less for microwave ovens than many other legitimate radiation sources, is considered an insignificant clinical problem by the medical profession, and is to be under effective control by pacemaker susceptibility standards expected to be promulgated by FDA under the 1976 Medical Service Safety Act. In most cases the proponents of such regulations have dropped their efforts after a full factual discussion has been presented.

COMAR has commented to the Bureau of Radiological Health and the Technical Electronic Products Radiation Safety Standards Committee (advisory to the HEW Secretary) on various proposed standards. In particular, it has opposed the requirement of warning labels on microwave ovens. The requirement was promulgated but with the possibility of exemption provided. COMAR in the last two years has opposed a proposed emission standard on microwave diathermy applicators because it is overly conservative, would cause the one U.S. manufacturer of such diathermy to cease production of such devices and would discourage extension of such diathermy to new objectives such as cancer therapy. COMAR supported the medical users of such equipment who felt a better control basis is the effective employment of exposure standards under occupational controls. It is incongruous that BRH appears concerned over the potential deleterious effects of low-level exposures in this situation where a twenty-five year record of safe therapy to the patient or practitioners has been confirmed[9] and a different branch of HEW prohibits[21] the sale of such diathermy unless the power level is high enough to produce significant heating—the only validated basis of therapeutic effects. This controversy should remind one that if important low-level "nonthermal" effects did exist, they surely would be exploited by the medical profession and present industry with a new market.

COMAR members have provided information to a radio broadcaster whose transmitter was alleged to be a potential "radiation" hazard by an abutter who planned to develop the land near the transmitter. This was an example of extension of "microwave" fears to frequencies well below the resonances of the human body and for which existing standards are believed conservative. It is also another example where potential interference with home electronics is associated with "radiation" hazard.

COMAR has responded to many articles in the press and programs in the broadcast media which have distorted the nature of non-ionizing radiation hazards Most recently COMAR has responded to the articles[22] by Paul Brodeur on "microwaves", by letter and by issuing for public release a detailed critique and rebuttal of Brodeur. The latter had implied that the military, government, industry and the scientific community were engaged in covering up serious potential hazards of non-ionizing radiation and that serious potential hazards to the general population existed from such radiation. COMAR found Brodeur's thesis unfounded and the publication of his articles a disservice to the general public.

COMAR has consistently supported an effective program of research on the bioeffects of non-ionizing radiation and has sought to inject professional society influence into the planning and review of such research. Because COMAR believes a healthy arrangement should include non-government as well as government personnel in research review panels, COMAR with the support of the President of the IEEE, wrote the Secretary of the Department of HEW in 1974 protesting plans to abolish a research review panel containing some non-government scientists.

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[20] Office of Telecommunications Policy, Report on "Program for Control of Electromagnetic Pollution of the Environment: The Assessment of Biological Hazards of Non-Ionizing Electromagnetic Radiation," (March 1973); also selected reports from EPA in recent years.

[21] Report to the Senate Committee on Government Operations by the Comptroller General of the United States, *Stronger Measures Needed to Insure that Medical Diathermy Devices are Safe and Effective*, U.S. General Accounting Office, HRD–76–153 (Sept. 2, 1976).

[22] Paul Brodeur, "Microwaves," New Yorker Magazine, (Dec. 13, 20, 1976).

COMAR, it must be repeated, strongly supports programs of research on bioeffects of non-ionizing radiation—but not for the wrong reasons which are suggested in the press. There is no crisis—no imminent health hazard from low-level NIR. It would be very sad if the great nation of the United States felt that research in this field is justified only if there is a public health crisis or even problem. Because electromagnetic technology pervades modern society in a host of ways it should be self-evident by the spirit and ideals of science that potential side-effects and interaction with biological organisms should be investigated. Potential payoff to society may not be predictable if it is truly good science but one can speculate at least that such research will

(*a*) permit more accurate safety standards with a more exact knowledge of safety factor as a function of frequency, exposure duration and many other variables,

(*b*) permit the development of new medical applications such as the use of hyperthermia in cancer therapy,[23]

(*c*) seek out potential biological applications—e.g., insect or weed control with less pollution,

(*d*) create useful spin-off knowledge of use to the industrial heating and microwave oven businesses. Problems of interaction of radiation with animals and the heating of foodstuffs and other materials are closely analogous.

In reviewing the status of today's research in the U.S., COMAR finds, however, that there are several aspects that suggest possible improvements in the planning, execution and reporting of this research.

1. In Fig. 7 we show a rough picture of the distribution in the spectrum of research on bioeffects of non-ionizing radiation in 1975. This refers to the number of projects in each spectrum segment which are reported in the annual report[24] for 1976 from the Office of Telecommunications Policy on this subject. The secondary peak of activity at very low frequencies reflect the special concerns over Project Seafarer. Otherwise, the research is concentrated in the conventional "microwave" region of 1 to 10 GHz. This is somewhat explained by the fact that most research is done with small animals, particularly rats and mice, for which experiments around body resonant frequencies are quite convenient in this frequency range where inexpensive power sources exist and exposure chambers can be of convenient size.

Since the primary interest is in potential hazards for man this research should be broadened to more clearly indicate how results are extrapolated to man. At present, strictly speaking, most research results relate only to small animals.

One meaningful action would be to extend the research with small animals over a broad frequency range, at least a decade, to verify the frequency dependence of effects which is expected to peak at some resonant frequency range.

Second, more specific research on both physical and biological aspects of "scaling" from animals to man should be performed. Besides theoretical work this may involve experimental work with phantoms of varying size over broad frequency ranges, and more direct exposure studies with larger animals. It is to be noted that for man that the expected resonance regime is in the VHF part of the spectrum with a rapid decrease of absorption for frequencies below 20 MHz and a transition to surface heating at frequencies much higher than the VHF range.

2. It is recognized that good research effort in this field requires truly interdisciplinary cooperative effort. There exists good research teams of this type at various universities and government research laboratories. Still the field is still dominated by engineers. Perhaps this is natural because most of the meaningful and more easily understood aspects of the problem are physical in nature. Practically all of the seminars and symposia, as well as journal publication in this field, are conducted with the cooperation of engineering societies.

It would be desirable if there were more involvement by the professional societies of the life sciences and the medical profession. It is understandable that the medical societies are little involved since there is essentially no or little confirmed evidence of injuries to humans from radiation exposure to RF/microwave energy despite the 25-year interest in this subject as a research area. Nevertheless, if the potential hazards are to be seriously considered, it would be productive if the professional societies in the life and medical sciences participate more specifically in support of symposia, journal publication and peer review and assessment of ongoing research. An effort in this direction is being conducted by the Microwave Theory and Techniques Society of the IEEE and the International Microwave Power Institute. These organizations hope to hold a special meeting of representatives from various professional societies during jointly sponsored symposia activities in June 1978 in Ottawa, Canada.

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[23] "Proceedings of the International Symposium on Cancer Therapy by Hyperthermic and Radiation," American College of Radiology (1976).

[24] Office of Telecommunications Policy, Fourth Report on "Program for Control . . . Radiation," (June 1976).

3. More effort be assigned to replication of research yielding controversial results. Often such research is not followed up by even the original investigators and remains a reference in the literature. If the research is felt to be valid, it certainly should be refined and extended to other animal species, frequencies, etc. On the other hand, if it is felt to be invalid, research to replicate the experiment will be a most convincing way of correcting the validity of what is in the published literature.

4. More research on bioeffects above 30 GHz should be done. Recent Soviet research,[25] and sophisticated physical theory[26] suggest frequency-specific and possibly athermal mechanisms of interaction with biological macro-molecules. This region of the spectrum has essentially no practical use at the moment. On the other hand, this situation offers society an ideal opportunity to explore potential bioeffects before extensive use of this part of the spectrum becomes a reality. Furthermore, it is possible that bioeffect research above 30 GHz may uncover beneficial applications and help stimulate commercial and medical uses.

5. It is already known[23] that there is a potential beneficial use of microwave heating in cancer therapy. The problems of microwave heating, both physical and biological, are not trivial. This is recognized in one NSF Workshop[27] for example. Similar physical problems exist in industrial heating, microwave ovens and medical applications.

Because of potentially great societal and economic benefit, research on the beneficial applications of microwave heating should be increased. This should involve all aspects of the research process and not just clinical studies with existing apparatus. Provision for possibly more optimum equipment involving new frequencies and new techniques should be made through more basic and exploratory research and a broader frequency allocation policy for ISM applications. Such a policy has been proposed by various groups including the International Microwave Power Institute[28] in efforts to influence the World Administrative Radio Conference which will be held in 1979 and will determine international agreements on frequency allocation likely to hold till the year 2000.

Lastly, we believe that there is a real need for public education on this subject—or more broadly, the nature of electrical or electromagnetic energy and its hazards. There has historically been frequent eruptions of irrational attitudes to electricity beginning with the fear of the electric lamp[29] a century ago. In the first half of this century there occurred a great amount of research on lower frequency diathermy (below 100 MHz) which led to many claims of dramatic non-thermal medical uses and applications based on a variety of speculative mechanisms. This led to industrial and medical exploitation which was later condemned[30] [31] by the medical profession. By World War II the latter concluded that "the burden of proof still lies on those who claim any biologic actions of these currents other than heat".[30] By contrast, when microwave diathermy as a therapeutic heating agent was introduced in 1950 it was considered well researched before clinical use.[31]

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[25] Summary of Papers on Biological Effects of Millimeter Waves, Soviet Physics Usp. 16, No. 4. pp. 568–579 (Jan-Feb. 1974).

[26] H. Fröhlich, "Evidence for Bose Condensation-Like Excitation of Coherent Modes in Biological Systems," Physics Letters 51A, No. 1, pp. 21–22 (Jan. 27, 1975).

[27] National Science Foundation, "Workshop on Future Directions of Electromagnetics of Continuous Media" (Dec. 1972).

[28] "IMPI Position Paper on Frequency Allocation Matters," Int. Microwave Power Institute, Edmonton, Alberta, Canada (1976).

[29] See for example J. of Microwave Power 11 (1), March, 1976; also Ref. 1, page 7.

[30] Editorial, "Microwave Diathermy—A double Progress," Arch. Phys. Med. (Jan., 1950).

[31] W. Bierman, "The Medical Applications of the Short-Wave Current," Williams and Wilkins Co., Baltimore (1942); page 114.

Since World War II with the introduction of the higher microwave frequencies into practical use, there have developed various legendary and almost fabled beliefs about microwaves, often associated with ESP or other pseudo-scientific subjects. A review[32] of these beliefs and how they appear in the contemporary scene has been made by Dr. Don Justesen, a member of this committee. It is attached as Appendix B.

It is apparent that there is a need for better public education on the nature of electromagnetic energy, its benefits and potential hazards even among sophisticated elements of our society. Topics that need to be clarified include:

(*a*) the fact that electromagnetic energy associated with the spectrum from ordinary electricity to visible light is non-ionizing and is not equivalent to the "radiation" associated with x-rays or nuclear systems which display potential for cumulative and more insidious effects;

(*b*) the fact that non-ionizing electromagnetic energy has been in use in many areas of modern society for many years without validation of serious human injury due to radiation effects;

(*c*) a better understanding of what modern bioeffect research is doing and what it means—for example, that effects, like sensation, do not necessarily imply hazard. The common experience of static shock after a walking on a rug is an example of significant localized electrical energy;

(*d*) the beneficial uses of electromagnetic energy ranging from household electricity, broadcasting to medical applications;

(*e*) the fact that sufficient understanding of the effects of electromagnetic energy to protect against known thermal hazards has been available for years. The key papers of Mumford,[33] a member of this committee, and Kalant[34] in the early sixties provided an authentic engineering and medical assessment of potential hazards. Since then the works of leading researchers like Schwan,[35] Michaelson[36] and Guy[37] have improved and extended this understanding toward a more exact quantitative formulation. Nevertheless, the conclusion of Kalant appears as valid today as it was earlier; namely, "practical protection of human beings against damage due to excessive microwave energy appears to require chiefly the application of common sense and sound engineering directed against known dangers, rather than a search for new and as yet unrecognized dangers".

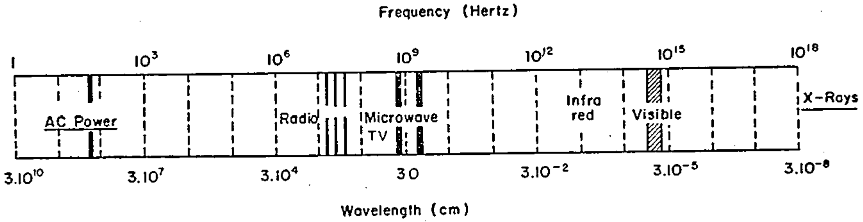

FIGURE 1.—The electromagnetic spectrum.

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[32] D. R. Justesen, "Diathermy Versus the Microwaves and Other Radio-Frequency Radiations: A Rose by Another Name is a Cabbage," Radio Science, Vol. 12, No. 3 (May-June 1977) (in press).

[33] W. W. Mumford, "Some Technical Aspects of Microwave Radiation Hazards," Proc. IRE 49, pp. 427–447 (Feb. 1961).

[34] H. Kalant, "Physiological Hazards of Microwave Radiation; A Survey of Published Literature," Canad. Med. Assoc. J. 81, pp. 575–582, (Oct. 1, 1959).

[35] H. P. Schwan, "Interaction of Microwave and Radio Frequency Radiation with Biological Systems," IEEE Trans. MTT–19, pp. 146–152 (Feb. 1971).

[36] S. M. Michaelson, "Human Exposure to Nonionizing Radiant Energy-Potential Hazards and Safety Standards," Proc. IEEE 60, pp. 389–421 (April, 1972).

[37] C. C. Johnson and A. W. Guy, "Nonionizing Electromagnetic Wave Effects in Biological Materials and Systems," Proc. IEEE 60, pp. 692–718 (June 1972).

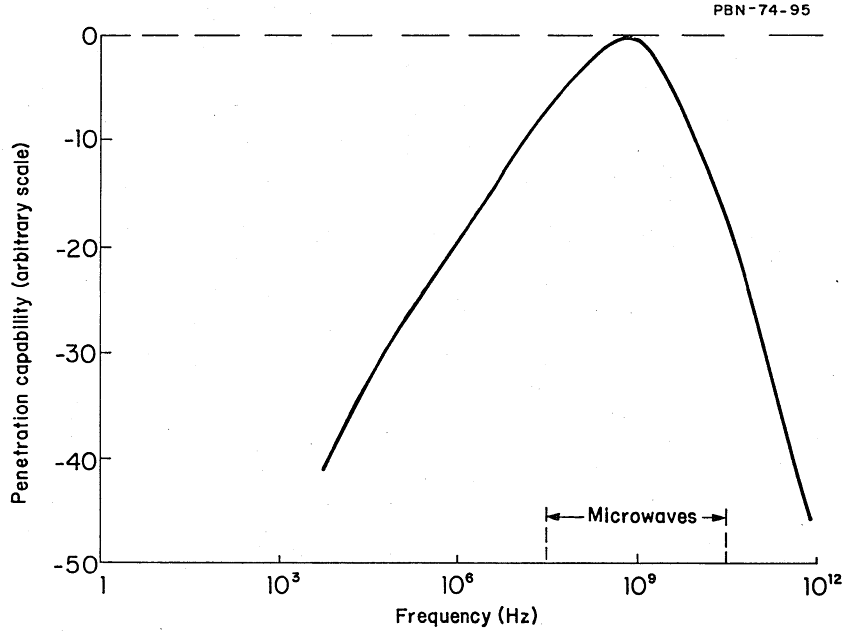

FIGURE 2.—Sketch of penetration capacity as a function of frequency.

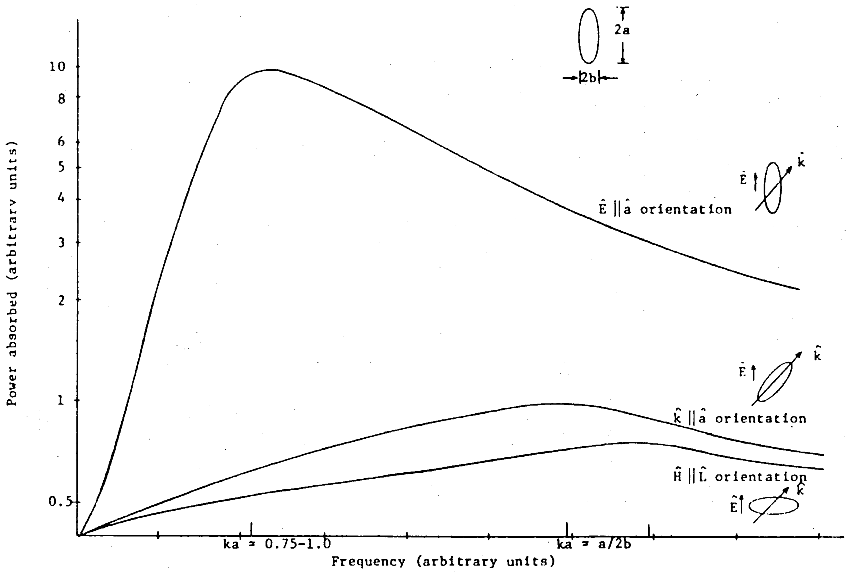

FIGURE 3.—Typical RF absorption curves for animals and bodies of prolate spheroidal shape. (Reproduced from reference 6.)

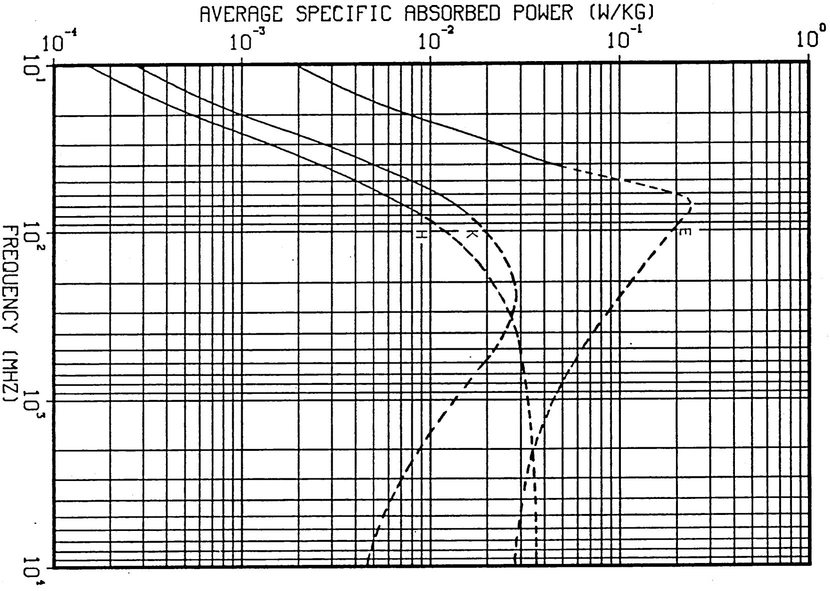

FIGURE 4(a).—Average specific absorbed power in a prolate spheroidal model of an average man, for the three standard polarizations. a=0.875 m, V=0.07 m^3. Incident power density is $1 mW/cm^2$. (Reproduced from reference 7.)

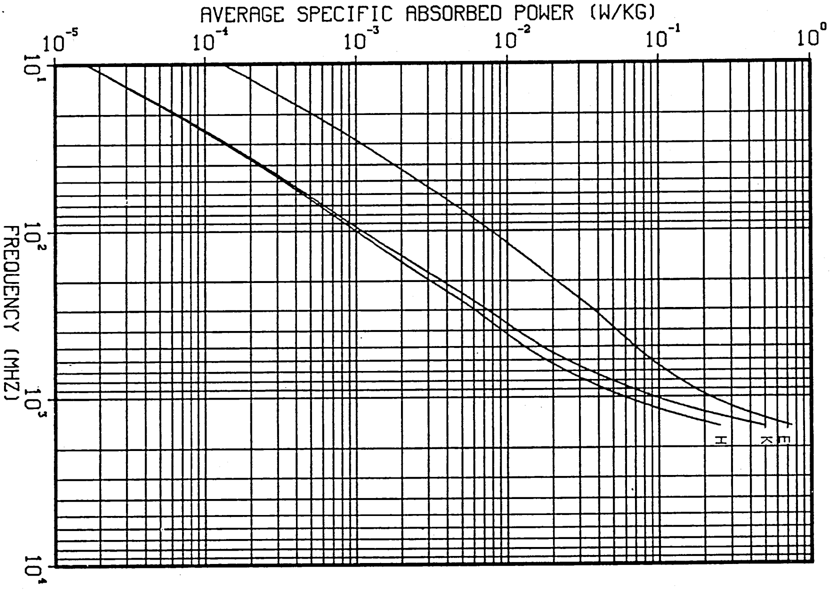

FIGURE 4(b).—Average specific absorbed power is a prolate spheroidal model of a small mouse, for the three standard polarizations. a=0.027 m, V=1.5 x 10^{-5} m^3. Incident power density is 1 mW/cm^2. (Reproduced from reference 7.)

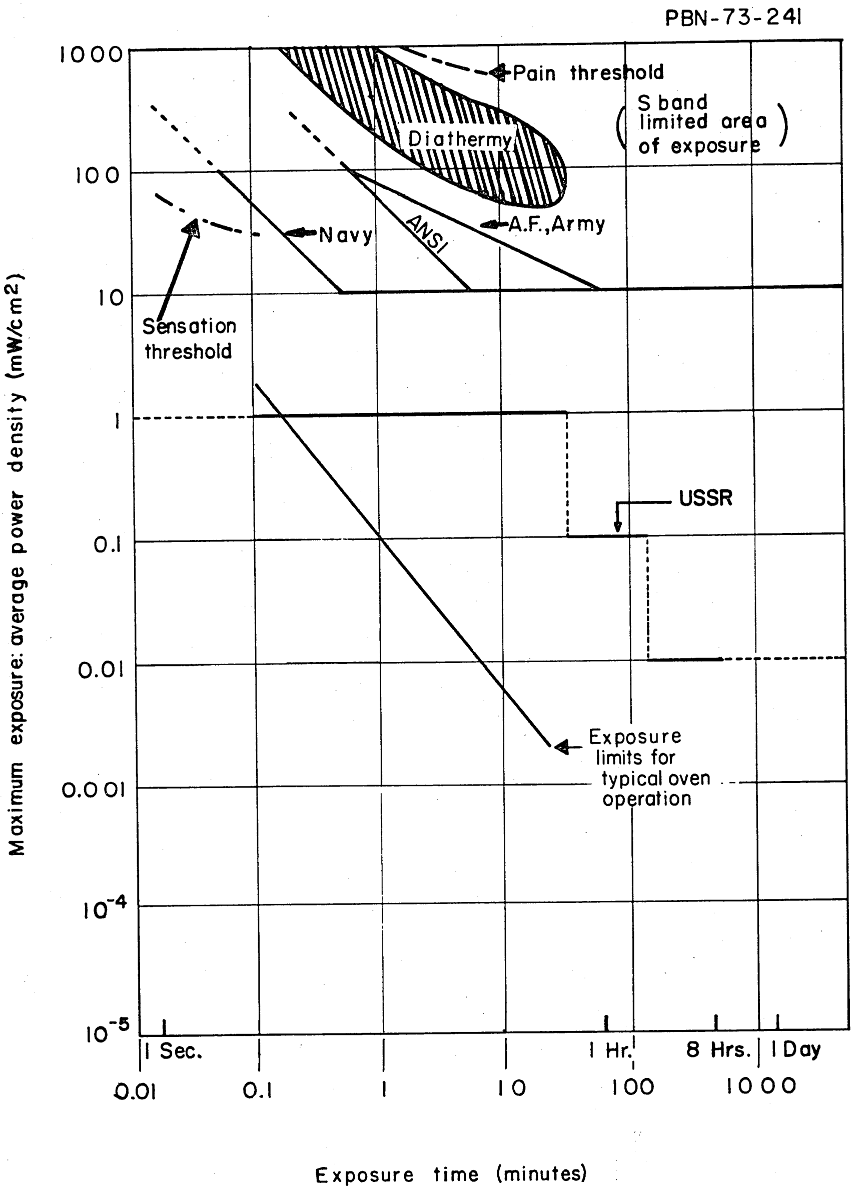

FIGURE 5.—Principal exposure standards and comparison to maximum probable exposure near microwave ovens, diathermy exposure, and pain and sensation thresholds.

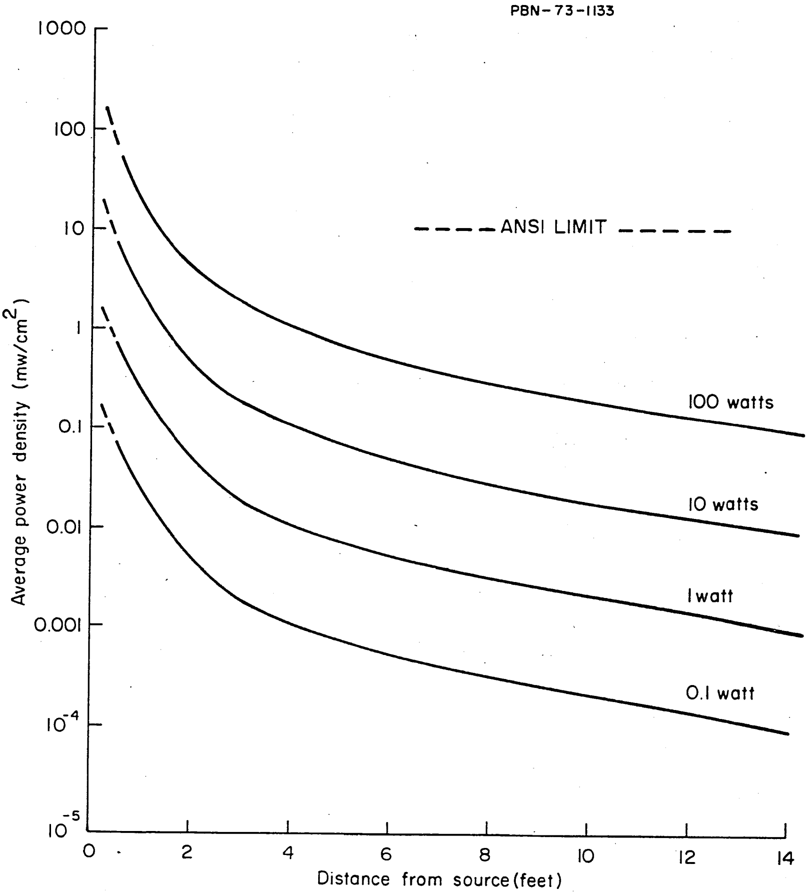

FIGURE 6.—Dependence of leakage power density on distances from a small leakage source.

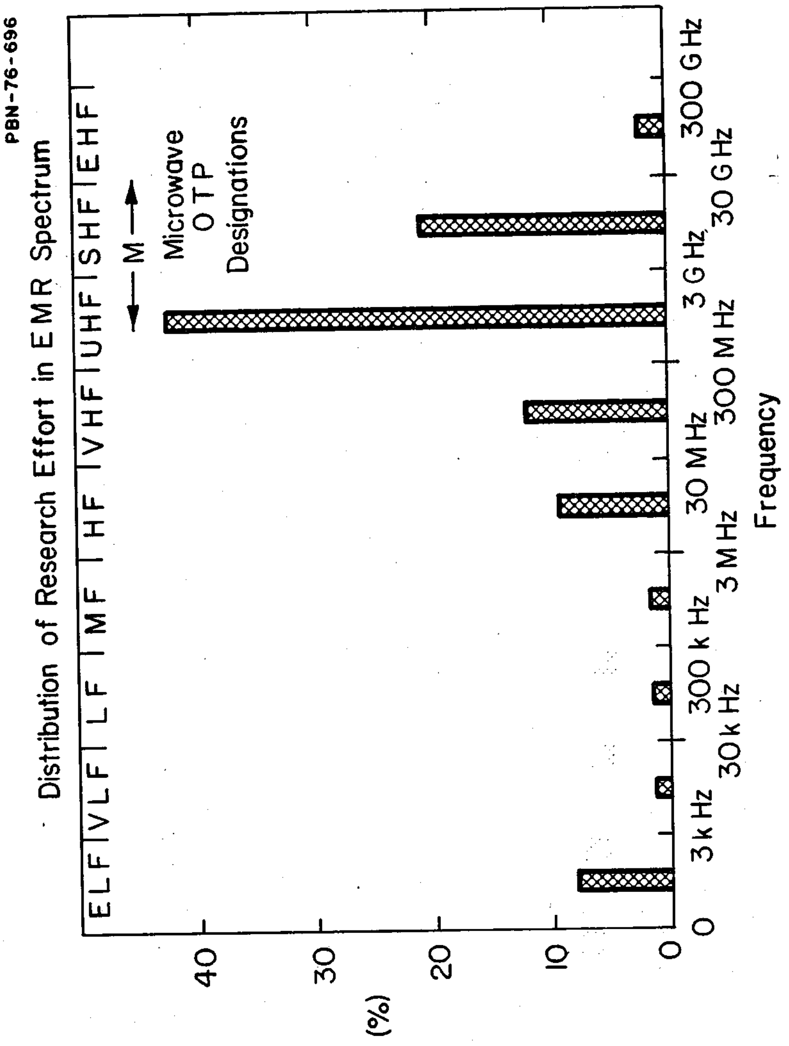

FIGURE 7.—Rough depiction of spectral distribution of research on bioeffects in the United States during 1975.

It is helpful at this point to quote a principal conclusion from the paper by Justesen (Appendix B), viz: "The assumption of hazardous nonthermal effects at low densities of radiation, which are suspected by some but are as yet unsubstantiated by anyone, is a fabrication from the whole-cloth of fear. This fear, which feeds on the absence of verified or verifiable evidence, is hampering basic studies and may thereby restrict medical development and application of radiofrequency radiations."

It is the aim of COMAR to help achieve rational perspective in our society with regard to potential hazard of non-ionizing radiation. It would be very desirable if efforts toward public education could be expanded and improved. It should be possible for government agencies (e.g., NSF or the National Academies) to sponsor and supervise the production of effective educational material, not only for the printed media, but also radio and television.

APPENDIX A.—IEEE COMMITTEE ON MAN AND RADIATION

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APPENDIX B.—DIATHERMY VERSUS THE MICROWAVES AND OTHER RADIO-FREQUENCY RADIATIONS: A ROSE BY ANOTHER NAME IS A CABBAGE[1]

(Don R. Justesen[2] Laboratories of Experimental Neuropsychology, U.S. Veterans Administration Hospital, Kansas City, Mo.)

There are symptoms of schizophrenia in the body scientific with respect to the mixed but fervent attitudes of its constituents toward the potential perils of exposure to microwaves and other radio-frequency radiations. The Rose: exposure of human beings to fields of high power density is common, therapeutic, and viewed with sanguinity in some sectors. The Cabbage: in other sectors the suspicion that even weak fields are present raises the pejorative finger of anguish and alarm. The paradox is explored in terms of historical, geographical, personal, impersonal, and nominal manifestations. Subsequent discussion of both simple and compelx termal effects of radio-frequency radiation is followed by several conclusions. Among them are: (1) Focal or general thermal insult from simple heating of tissues can in principal result from exposure to fields as low as or even lower in density than 1 mW/cm ^{2}, although the practical likelihood of damage at this density is remote. (2) Consensual resolution as to the existence and nature of weak-field hazards, thermal and nonthermal, will only be reached when dosimetry—the measurement of *absorbed* energy—is adopted as a rule of procedure in the laboratory. (3) The assumption of hazardous nonthermal effects at low densities of radiation, which are suspected by some but are as yet unsubstantiated by anyone, is a fabrication from the whole-cloth of fear. This fear, which feeds on the absence of verified or verifiable evidence, is hampering basic studies and may thereby restrict medical development and application of radiofrequency radiations.

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[1] Based on an address at the plenary session of the 1975 meeting of Commissions I–VI and VIII of the U.S. National Committee of the International Union of Radio Science, which was convened October 20–23 on the Boulder campus of the University of Colorado.

[2] Also with the Department of Psychiatry, the University of Kansas School of Medicine, Kansas City, Kansas.

I am honored not only to sound a biological keynote but also to comment on the recent marriage of biology and radio science within the organizational structure of USNC/URSI. No shotgun marriage this but a carefully contemplated union with the Union that was brought about through the efforts of many individuals, as detailed in a companion paper [Johnson, 1977] in this issue. Speaking for the engineers, biologists, and physicians who are studying biological effects of radio-frequency electromagnetic radiation, I can attest the need for a home and a haven wherewithin to organize, articulate, and disseminate the products of our endeavors. We have grown travel-weary and footsore during the past decade in attempts annually to attend a dozen different meetings of differing professional societies. We have long desired a printed forum for our researches since few of us have ready access to all of the many journals that carry our published works. There is every reason to believe that USRI will come to be the major medium through which our eclectic assembly of scientists can congregate and communicate. To all of the engineers and radio scientists of the Union who may wonder with some trepidation about the impact of the "blood and gore" of biology on the spotless edifice of USRI, let me say that we shall try to justify your welcomed offer of haven by deporting ourselves hygienically and well.

I should like to explore several facets of a paradox that is becoming increasingly manifest to those of us who labor at the intersection of microwaves and medicine. By way of illustrating the paradox, I shall visit a bit of semantic violence on Gertrude Stein's celebrated tautology: the microwave rose is a rose is a cabbage. But if the rose to a nose is a fragrant boon, the malodorous cabbage is a bane. Resolution of this seeming contradiction is not forthcoming, moreover, when one cuts through the trappings of metaphor and considers the opinions of the microwave experts.

Expert—and not so-expert—opinion ranges the spectrum from an unflinching insistence that exposure to all but thermally poisonous fields is without adverse consequence, through several shades of agnosticism, to the frightening view that immersion in even the weakest electromagnetic field portends psychic and physical harm. The proponents of the view that weak fields are harmful are a mixed lot. Some are sensationalists. Some are scientifically naive. But other are scientists of sincerity who are quite aware that man and his forebears have evolved as recipients of natural electromagnetic radiations of cosmic, solar, and terrestrial origin. Theirs is the belief that the augmentation of natural by man-made fields may be the cubit that tilts and topples the balance of nature. A possible parallel is that of thermal pollution of streams and rivers. Electrical generators that use water to cool thermonuclear reactors may elevate downstream temperatures by one or two degrees; the relatively minuscule thermal change from, say 283 to 285 K. can result in wholesale changes in the local ecology [Environmental Protection Agency, 1972]. I hasten to point out, however, that the parallel is not complete. While man has increased the level of radio-frequency electromagnetic radiation many orders of magnitude above the natural background, evidence of functionally correlated changes in the flora and the fauna is wanting. Alterations in the populations of algae and fish are reliably observed in the warming of their waters but the existence of pollution by radio-frequency energy is at best an unsubstantiated suspicion.

By way of anticipating my conclusion—and to arm you with that ennobling skepticism that is the midwife of all true science—I wish to offer an explanation for the strongly held if highly divergent views with respect to the existence/nonexistence of electromagnetic pollution. Simply put, the intelligent human being when faced with uncertainty about a potentially pressing problem often tends to polarize and then to theologize his views. What emerges is a kind of evangelical faith that is based neither upon evidence nor against it but on its absence. The result is an arena populated by believers, agnostics and atheists—but even the agnostics are devout. Stated more formally: Fervency of belief in some potential ill is inversely related to the amount of evidence that confirms or negates its existence.

I shall return later to this canon of fervency after documenting the paradox of the microwave rose that smells like a cabbage. In my documentations I shall be referring not only to the microwaves but also to the longer wavelengths of electromagnetic energy that in combination comprise the radio-frequency spectrum.

The historical paradox.—The paradox of rose and cabbage exists in many forms but none is so compelling as that portrayed in recent medical history. During the latter half of the last century, Franklinisation—electrical stimulation of patients at a mix of frequencies—was introduced and used to treat neurasthenia, a curious cluster of symptoms that variously includes headache, insomnia at night, sleepiness in the daytime, lethargy, muscular weakness, impotence, and what in modern American parlance is sometimes labelled "the blahs." An engraving (Figure 1) that was reproduced in a 19th century medical journal is captioned [Stein, 1974]:

"Franklinisation or static electricity is therapeutically indicated for neurasthenia, migraine and hysteria. The patient, placed on an insulating podium, immediately feels, once the apparatus begins to function, a sensation comparable to that of a gauze veil lightly brushing against his face. A sudden discharge resulting in a spark that lends a certain pallor to the teguments may be caused by holding a metallic ball near to the patient. In the case of the muscles, quite energetic tremors and contractions in proportion to the length of the sparks can be observed."

Paradoxically, the one-time 19th century cure for neurasthenia is now being advanced as its cause. Especially in the Soviet sector of eastern Europe, radio-frequency radiations that extend from the extremely low frequencies (ELF) through the microwaves are being blamed for induction of the neurasthenic syndrome [cf. Marha, 1970, with Tolgskaya and Gordon. 1973].

The geographical paradox.—Closely related to the historical is the geographical paradox. To judge by exposure standards, microwave radiations are much more dangerous in eastern Europe, where a limit of 10 $\mu W/cm^2$ prevails, than in western Europe and the USA, where the limits are usually a thousand-fold higher. Correlated but inversely so with these differing limits is the much higher incidence in reports of neurasthenic disorders among eastern Europeans. Whether the higher incidence is a reflection of failures to adhere to exposure standards, of greater susceptibility to radiation by inhabitants of eastern Europe, of more sensitive medical measures or more candid medical reporting, or of a geopolitically inspired mass hysteria, is impossible of reckoning at the present time. Some support for the last mentioned possibility comes from Japan, which has the highest per capita ownership of microwave ovens on this beleaguered planet. After the April 1973 issue of Consumer Reports received coverage in the Japanese press—which issue featured a condemnation of all microwave ovens because of their failure to emit zero-levels of radiation—there was a flurry of citizens who reported to clinics with complaints of radiation-related symptoms. The proximity of Hiroshima and Nagasaki, with their horrifying remnants of atomic radiation, could certainly sensitize some members of a population to respond hysterically to the threat of any kind of radiation. In homage to the hallowed doctrine of science that all empirical propositions are not only suspect but possible, one must concede that the evidence for hysteria may alternately be taken as evidence that some sick people in Japan simply did not know the source of their symptoms until they were enlightened by writers for the Consumers Union.

It would be unfair and invalid to present the eastern European countries as a stereotype. Not all encounters with radio-frequency radiations are viewed by their inhabitants with alarm. Two Polish engineers [see Bem and Trzaka, 1977] have recounted how a pair of sparrows invaded a government-imposed, 10-kilometer radius of restriction to build a nest next to the coaxial feed-point of a megawatt radio transmitting antenna. Across several months of time, during which the birds mated, nested, tended their eggs and then their fledgling offspring, the while in electromagnetic fields of extremely high density, the engineers from a vantage of safety conducted impromptu ethological studies. No ominous signs of deviant behavior, not even evidence of a low-grade avian neurasthenia were observed. Near summer's end when the fledglings had completed flight training, the neophyte family of sparrows took to wind and headed south toward warmer climes. The engineers concluded, perhaps a bit tongue-in-cheek, that what the birds did not know had not hurt them.

The personal paradox.—In the abstract, I stated that there are symptoms of schizophrenia in the body scientific. More specifically, there are individual scientists who hold a rose in one hand and a cabbage in the other. I am not referring to the ambivalence of a few scientist-chameleons who readily change their colors in pandering to a particular audience but of individuals whose minds and attitudes are truly split on the question of microwave hazards. Professor Arthur Guy recently told me of actions by a committee on human studies that dramatically illustrates the paradox. Before the committee were two requests: one, a clinical proposal to expose a patient continuously for 20 min to a microwave field the averaged power density of which would be 200 mW/cm^2; the other, an experimental proposal to expose for one or two minutes at a time a volunteering scientist to a field 200 times less intense. The former request was approved, the latter, denied!

A moral is imbedded in the personal paradox, what many of us have come to expect in this cerebrally softening Age of Aquarius: We are often willing to risk clinical application of exotic agents but we more often will not countenance lesser risk for the sake of gaining a scientific understanding of their modus operandi.

Illustrative of the relative ease of applying microwave energy in the clinic is a recent report in the journal Obstetrics and Gynecology by Daels [1973], a Belgian gynecologist. Over a period of time, Daels radiated the abdomens of 1,000 women during labor with 2450–MHz microwaves. The radiations were sufficiently intense to warm the mother's skin; also, through placental circulation of heated maternal blood, the fetal temperatures was increased by more than one Celsius degree. Comparisons of ease of delivery, of time in labor, of quantities used of a narcotic analgesic, and of healthiness of newborn infants were made with another 1,000 women who delivered under conventional conditions. The radiation-assisted delivery was superior on all counts (Table 1, Figure 2).

Dael's data are definitely a bouquet of roses but as yet unanswered are two questions. First, since sham-radiation was not used in the control treatment, how much, if any, of the greater ease of delivery is adducible to placebo effect? And second, what are the latent effects, if any of the radiation on the progeny? Depth of penetration into biological materials of 12-cm microwaves is not great and only a small amount of radio-frequency energy in all likelihood reached the fetuses, but those who believe in perils of weak fields will still ponder the possibility of adverse consequences. One hopes that Daels will perform follow-up studies; his is a unique opportunity to help dispel or confirm the possibility of dangers of microwave irradiation of the human fetus.

The impersonal paradox.—On occasion, it is the experiment, not the experimenter, that carries a mixed bouquet of roses and cabbages. Work reported by Prausnitz and Süsskind [1962] is a case in point. The investigators conducted a long-term study of male mice, 200 of which were irradiated with 3-cm microwaves for 4.5 minutes a day, five days a week, for a maximum of 59 weeks at an incident power density of 100mW/cm^2. Sham-irradiated controls numbered 100. Highly reliable evidence of radiation-induced testicular damage was observed. There was also suggestive evidence that the thousand-plus radiation treatments, each of which produced an averaged rise of body temperature of 3.3°C, resulted in leucosis, a neoplasm of white blood cells. Contrasting with these cabbage-category findings is another that can only be classed as a coming up of roses. The authors found that "longevity of the mice [was] not adversely affected" by the radiation; indeed, my analysis of their data (Figure 3) reveals that the radiated mice, 64% of which were living when half the controls had expired, lived reliably longer ($x^2 \sim 5.4$: at 1 df. $P < .02$).

Related findings were obtained in my laboratory [see Rhein, 1972] by two medical students. Sheldon Preskorn and William Edwards, who were attempting to learn whether four brief but intense, in utero exposures and 36 postnatal exposures to 2450–MHz microwaves would shorten life-span of mice. All of their fetally and postnally radiated or sham-radiated mice were injected during the 16th day post partum with a homogenate of a lymphoreticular-cell sarcoma. The rationale for their injection was to induce a rapidly growing malignancy that would shorten the life-spans of control mice to about three months. The expectation was that radiated mice would have an even shorter life-span. The experiment was a failure in the sense that, even after three months had passed, fetally irradiated mice had a low incidence of "takes"—only 3 of 24 mice had developed a tumor as compared with 11 of 24 mice that received sham-radiation as fetuses (Fgiure 4). The longevity study was aborted to permit histological examinations of the mice. While the postnatal treatments had little effect on rates of tumor induction, there was histological evidence that these treatments retarded growth of tumors: indeed, in a few cases, tumors underwent virtually complete regression. In a follow-up study [Preskorn et al., 1977], measures of longevity revealed that fetally irradiated mice, whether or not tumors were later induced, lived longer on the average than controls.

The longevity data on the animals without tumors are comparable to those of Prausnitz and Süsskind (cf. Figures 3 and 5).

The nominal paradox.—Shakespeare's famous metaphor, "A rose by another name would smell as sweet," is belied by the pervasive tendency of human beings to be led by labels. A "pre-owned" automobile is superior to a used car. Statesmen are better than politicians. A sanitary technician is nobler than a trash hauler. Several months ago, in sifting through the biomedical literature on radio-frequency energy I was struck by a polarity of labelling. In almost every instance of a report of beneficial effects, application of microwaves and other radio-frequency energy was referred to as diathermy. Conversely, where ill effects were suspected, they were attributed to radiation. In a flight of fancy, recalling the ancients who believed in the magical properties of names, I began to wonder if the perils of exposure to electromagnetic energy might be caused by the name "radiation"; if so, all hazards could be eliminated by the simple expedient of outlawing use of the term. A second sobering thought, still in the realm of fancy, focused on the horrors that would be visited upon mankind if some subversive group were to turn the tables and relabel a host of common encounters:

Basking in the sun would be
  Baking under solar radiations:
Spooning under the moon would be
  Spoiling under lunar reflections of solar radiations:
Reaching for the stars would be
  Retching under cosmic radiations.

Such simple acts as flipping a light switch, turning an ignition key, lighting a gas jet, grilling a steak, taking a hot shower, retiring under an electric blanket—each of these would bathe the individual in an additional flux of electromagnetic radiations, with the threat of atrophy and malaise for all.

Enough, now, of fancy and fantasy. What are the hard data, the solid facts upon which to make an enlightened appraisal of the biological risks of exposure to radio-frequency radiations? There is a scientific consensus that lengthy exposures to fields of high flux density, 100 mW/cm^2 and more, are thermally dangerous. There is an increasing prevalence of expert belief, if not an outright consensus, that lengthy exposures to fields between 1 and 100 mW/cm^2 may be thermally dangerous depending on a host of environmental, electrical, and systemic factors. To ilustrate by a hypothetical and highly unlikely "worst case": If an individual in severely compromised health with an elevated body temperature of 41° C (~106° F) were introduced to an environment of comparable temperature, 100% relative humidity and no air currents—and if he were exposed to a field of 1-mW/cm^2 density and of a frequency and polarity promoting maximum resonance—he would expire within minutes. His death would be hastened, moreover, if there were ghost-moding of radio-frequency energy within his skull or if there were other factors conspiring for concentrations of thermalized energy—"hot spots"—in critical structures of the central nervous system. Too, given the adverse environment I have described, the individual would probably die in a short time even without the exposure to radio-frequency radiation. While Nature often makes quantum jumps, she seldom draws sharp lines so I, perhaps, should qualify my arbitrary limits of 100 and 1 mW/cm^2. A nude man set loose in the frozen climes of the Arctic tundra in a driving wind would quickly expire unless he were gifted with placement in a 100-mW/cm^2 field. On the other hand, the worst case for peril in principle could go below 1 mW/cm^2.

Whatever the lowest time-intensity numbers that spell danger might be, the scientist-cum-evangelist will lash out with a pejorative tongue and argue, quite correctly, that my "worst case" is a scenario in which excessive heating is entertained as the sole source of peril. He will go on to argue that there are nonthermal hazards. In support of his argument, he will not define "nonthermal" or specify nonthermal mechanisms of peril, he will not specify conditions under which a thermal mechanism can be excluded but he will say that there are many gaps in scientific knowledge, particularly about the molecular and macromolecular workings of the central nervous system (minor premise: The brain is a mystery. Further, since the brain's workings are not fully understood, it is impossible to know what is going on when the organ intercepts an electromagnetic field (major premise: The brain field interaction is a mystery). Therefore (and it is this line of reasoning that fully unfurls the colors of the scientist-cum-evangelist), nonthermal hazards not only cannot be ruled out but must be given serious consideration.

Even the freshman student of logic will recognize the conclusion of the argument as a nonsequiter; ignorance of a subject-matter carries no warrant for any proposition or theory. It simply does not follow that lack of neurological knowledge opens the evidential door to nonthermal insult—or shuts the door on thermal mechanisms of insult.

Those of us who classify ourselves as agnostics on the likelihood of nonthermal hazards are to some extent to blame for the slipshod reasoning. For the sake of establishing safe limits of exposure, we subscribed for many years to the thesis that power densities of radiation below 1 mW/cm^2 are not thermalizing. By such a fiat we dismissed the good sense of science, which dictates that even the weakest radiation will heat, however slightly, the body that absorbs it. In effect we made pragmatic concessions to nonreality by saying two things: (a) if predicted rises of a body's temperature from an absorbed radiation are smaller than our thermometers can measure, then the radiation is nonthermal; and (b) when we do observe for thermal effects, we settle for the average temperature, ignore resonance, and dismiss the occurrence of nonlinear heating of tissues (hotspots). The folly of the flat was first revealed in an empirical study by Guy and Korbel [1972] was found that exposure of simulated rats to a continuous-wave microwave field with a carefully measured power density just below 1 mW/cm^2 resulted in hotspots the peak temperatures of which were sometimes more than three orders of magnitude above predicted average values. More recently, Gandhi [1974, 1975] has confirmed and extended theoretically what Schwan and his students [see Anne et al., 1961] demonstrated much earlier: the functions that relate incident energy to absorbed energy are shot-through with nonlinearities. In short, the power density of incident energy is often poorly correlated with the quantity of energy that is being absorbed by the biological target.

For more than a decade it has been my conviction that sole reliance on measures of incident energy by an investigator is the principal barrier to resolution of the thermal/nonthermal controversy [cf. Justesen and King 1970, with Justesen et al. 1971, and Justesen, 1975a]. Even as reliable therapeutic quantitation of ionizing radiations was not realized in the clinic until the concept of energy dosing was introduced, the biological scientists are unlikely to make much headway with the nonionizing radiations until comparable measures of absorbed energy are widely used and accepted. The number of investigators of biological effects of radio-frequency radiation who employ dosimetric measures is on the increase [cf., for example, Johnson and Guy, 1972; Guy, 1974; Ho and Guy, 1975; Phillips et al., 1975] but there are many who resist such measures.

Resistance to dosimetry in many instances can be blamed on habit—on the traditional reliance on densitometry. In a few cases, however, the argument is made that acceptance of dosimetry, which is predicated primarily on thermometry, thermography, and other calorimetric measures, would signify the investigator's acceptance of simple heating as the basis of any observed biological effect of radio-frequency radiation. Definitely a nonsequitur, this line of thinking is fallacious because use of a particular tool or method cannot commit the user to a theoretical position. The radiologist administers a given number of calorimetrically calibrated Rads of X irradiation to a patient but not for some commensurate heating effect—which, quite to the contrary, he is careful to minimize through use of filtration. Rather, having compensated for his filtration factor, he simply takes advantage of the correlation between kinetic ("heating") and photon ("ionizing") energies. Similarly, the use of a calorimetric dosimetry in biological studies of radio-frequency radiation takes advantage of the correlation between the strength of the electromagnetic fields in a biological body and the resulting thermal product. Instead of rejecting calorimetric techniques, the investigator who wishes to demonstrate effects that are not borne of simple heating should embrace them. One of the more forceful arguments that a biological effect is not based on simple heating would be the demonstration that its threshold or magnitude is uncorrelated with averaged quantities or rates of incorporation of radio-frequency energy. An effect that is dependent, say, on peak densities of energy would (or could be made to) exhibit zero-order correlations with averaged values of absorbed energy.

I hope at this juncture that I have clearly communicated two views: one, that systematic institution of dosimetry—measures of absorbed energy—in the laboratory should considerably advance our understanding of biological effects of radio-frequency radiation, whatever their basis; and two, that low-level effects are not necessarily of a nonthermal origin. Implicit in what I have said is another view that has been voiced before by many scientists, and disregarded by others. To demonstrate a biological effect of radio-frequency radiation is not perforce to demonstrate a peril. The criteria of a hazard are inclusive of but extend beyond the definition of "effect." However, one should not minimize the difficulty of distinguishing benign effect from hazardous effect; the distinction may be especially difficult in the clinic where destruction of a tumor by diathermy would certainly be hazardous for the malignancy and for the healthy tissues in which it is imbedded but would be of significant benefit to the patient.

Differing only slightly in semantics but of enormous importance is another distinction, that between the class of *thermal effects* and the subclass of effects based on *simple heating*. Excessive (simple) heating of a biological body, either focally or as a whole, would appear to be the basis of the confirmed instances of biological damage by radio-frequency radiations. There are, to be sure, potential nonthermal effects borne, e.g., of electrostriction and field forces [*cf.* for example, *Schwan and Sher*, 1969, and *Lin*, 1976] that may hold peril, but evidence in support of damage is lacking. There is also a well-confirmed thermal effect *not borne of simple heating* that has recently received much investigative attention. Originally described by *White* [1963] and more recently confirmed by *Foster and Finch* [1974] is the phenomenon of *thermoelastic expansion*. This complex heating effect occurs when a pulse of radiation of high peak density and sharp attack is absorbed by some medium. The sudden but minuscule thermalization of the absorbing materials—the averaged rise of Celsius temperature may be less than a millionth of a degree—because of the thermally-dependent densities of solids and liquids, launches a pressure wave. It is now believed by many scientists that the thermoelastic wave of pressure is the basis of the RF-hearing or Frey-effect, the perception of a clicking or popping sound by a human subject whose head intercepts a pulse of microwave radiation [*cf. Frey*, 1965, with *Justesen*, 1975*b*, and *Guy, et al.*, 1975].

Possibly linked to thermoelastic expansion is another biological effect, an increase in the penetrability of the blood-brain-barrier system of rats, which was first reported by *Sutton and Nunnally* [1973] and later confirmed by *Frey et al.* [1975] and *Oscar and Hawkins* [1975] Sutton and Nunnally did not measure the incident power density of their continuous-wave 2450-MHz field but did measure brain temperatures. A 25-min exposure that led to an elevation to 42°C produced a reliable penetration of the barrier. The studies by Frey *et al.* and by Oscar and Hawkins revealed that pulsed microwaves at low averaged densities near 200 $\mu W/cm^2$ are more effective than unmodulated fields in promoting alterations of the brain's permeability.

Since the Frey-effect and the alteration of brain-barrier permeability are produced by fields of relatively low averaged density, grounds certainly exist for entertaining suspicions of a weak-field hazard. But neither demonstration in the light of present knowledge can be taken as proof of peril. Undoubtedly you shall hear otherwise: the sensationalists, the scientifically naive, and the scientist-cum-evangelist whom I have referred to earlier will find a press that is eager to print allegations or even assertions to the effect that 'mysterious pressure-waves from electromagnetic fields are scrambling our brains and laying us bare to all manner of insult.'

During the years I have spent in the microwave laboratory, many colleagues have asked me whether I have fears and concerns for the living beings that are exposed to microwaves and other radio-frequency radiations. Concerns I do have, although most of them are not the sort that makes for ready copy in the *National Inquirer* or Jack Anderson's column in the *Washington Post*. One concern, already alluded to, is for the balance of reason, which to me seems more under threat than the balance of nature. The assessment of benefits and risks in a humane society must be undertaken but when suspicions of risk unqualified by verified evidence are heaped on the scales, a vicious cycling can be set in motion. Fear promotes suspicions, which may discourage or even prevent analytical study, which may result in more fear and suspicion. Suffice it to say that basic studies of the human response to radio-frequency radiations have been aborted and prevented in the past and are now being avoided, not because of demonstrated risks but out of fear—fear of the very unknowns that might be uncovered by judicious enquiry. The irony is that the existence of a peril—its discovery, characterization, and means of being brought under control—would likely be hidden under the same layerings of suspicion and fear.

A corollary concern relates to clinical application of radio-frequency radiation. It is reasonable to assume that a dearth of basic data and a plenitude of mordant suspicions will limit the physician in his therapeutic use of radiation. To the extent that he is limited, clinical and experimental medicine may be losing their best bet for unraveling one of the oldest of medical mysteries, the role played by fever in disease. By what means other than radio-frequency radiation could one "program" a fever of controllable duration and intensity in the experimental animal or in the patient?

I alluded earlier to the demonstration by Sutton and Nunnally that fever as induced by microwave irradiation of the brain can increase the permeability of the blood-brain barrier. It is plausible to conjecture that the barrier also falls during the course of "natural" fever. Nature, who designed the barrier, apparently to provide for a normally immunologically privileged brain, would appear to have created a portal that opens with an elevation of cerebral temperature. A hyperthermal portal would permit normally excluded antibodies and other defensive materials to enter the brain where, conceivably, they may lock in combat with infectious or other malignant agents. If Nature has designed such a portal, she certainly on occasion could use the assistance of the physician whose twofold tool of diathermy-and-antibiotics might reverse the course of a potentially fatal infection of the brain. The provocative findings cited earlier of enhanced longevity and of regression of tumors in mice after induction of fever by microwave radiation certainly lend credence to the view that the febrile state has survival value both clinically and in the natural scheme.

My speculation about the potential curative powers of microwave fever is tenuous but it highlights my greatest concern, one to which I pray this distinguished readership will give thoughtful consideration in its future deliberations and investigations: Will the medical potential of the radio-frequency radiations be fairly and fully assessed and realized, or will the microwave rose wither in the shadow of the cabbage?

Acknowledgments.—The opinions presented herein are not intended as expressions of official views of the U.S. Veterans Administration or the Federal Food and Drug Administration, both of which support the author's program of research.

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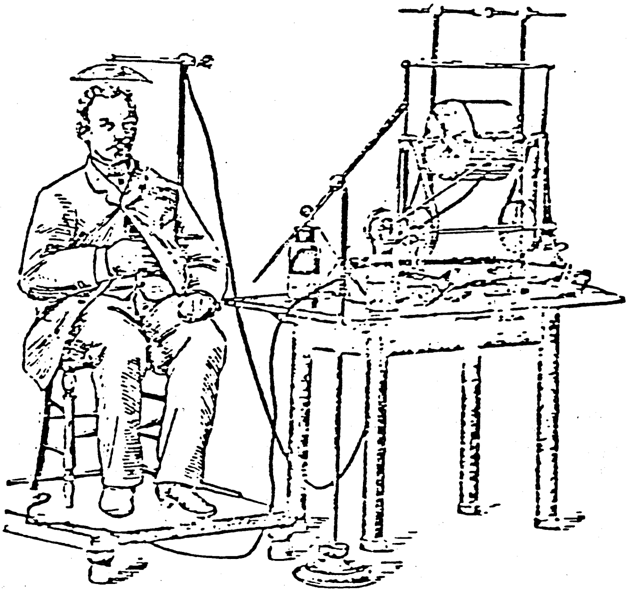
FIGURE 1.—Reproduction of a wood-cut engraving that was originally reproduced in a 19th Century medical journal. The apparatus is a hand-driven generator of electrostatic energy. Resulting fields—at a mix of frequencies because of a spark-gap—were capacitively coupled to a patient with the aim of controlling symptoms of neurasthenia, migrainous headache, and hysteria. The original caption is given in the text. (Reproduced from Stein [1974] with permission.)

TABLE 1.—Time in labor of 2,000 women during latent and active phases of the first stage of labor. Brief exposure of the abdomen to 2450-MHz microwaves during contractions was made of 1000 women, 399 of whom were primipara (delivering first-born); and 601, multiple (delivering their second or later baby). Control deliveries without radiation also numbered 1000 with respective numbers of primiparous and multiparous births approximating those of the radiated women. A reliable reduction in time of labor was associated with the microwave



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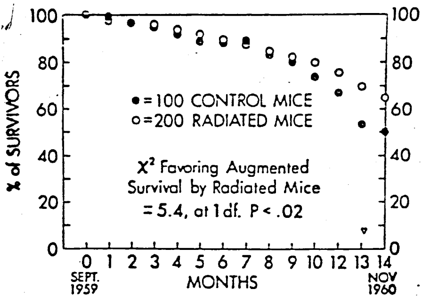
treatment as was the maternal dosage of a narcotic analgesic, meperidine. (Reproduced from Daels [1973] with permission.)

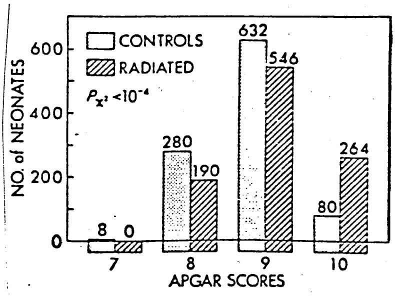
FIGURE 2.—Apgar scores, which measure the healthiness of a new-born on a 1 (worst) through 10 (best) scale, are shown for offspring of 1000 control mothers and 1000 mothers whose abdomens were radiated with microwaves for a period of 40 to 60 sec during a contraction. The number of microwave treatments of individual mothers ranged from 10 to 60. The number of infants from radiated mothers in the highest Apgar category of 10 is approximately 3. 5 times that of control infants. The highly reliable difference reflecting healthier infants from radiated mothers is presumably a reflection of shorter times of delivery and lesser maternal demand for a narcotic agent (Redrawn, with permission, from Daels [1973].)

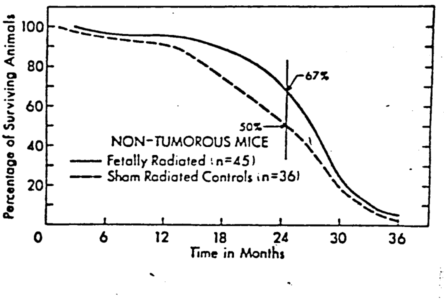
FIGURE 3.—Survival data on 100 mice that were sham-radiated and 200 mice that were radiated once daily for 4.5 min five days a week across 59 weeks by 3-cm microwaves of sufficient density (100 mW/cm^2) to increase body temperature by more than 3°C. In spite of a higher incidence of testicular damage and of cancer of the white blood cells, radiated mice lived longer on the average than controls. (Redrawn, with permission, from Prausnitz and Süsskind [1962].)

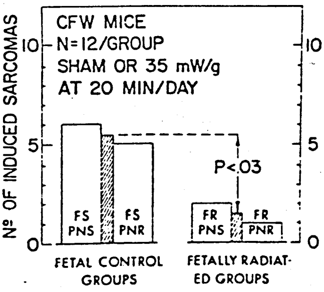
FIGURE 4.—Results of a factorial study of 48 mice in which an equal number of mice in each of four groups was fetally sham-irradiated or irradiated for 20 min in the 11th through 14th days of gestation by 2450-MHz microwaves at a dose-rate of 0 or 35 mW/g. After the 16th day post partum, during which all 48 mice were administered an agent that induces growth of a rapidly growing malignant tumor, a series of 36 consecutive daily exposures to radiation or sham radiation followed. (Key: F=fetal. PN=post natal. S=sham-radiation. R=radiation). Hatched areas between adjacent bars indicate the mean number of mice that developed a tumor from each of the two fetally sham-irradiated groups (to reader's left) and from each of the two fetally radiated groups (to reader's right). The respective mean percentages of tumor induction, 46% and 13%, suggest that intrauterine exposure to microwave radiation may enhance development of immunological competency. Post natal radiation had little effect on rate of tumor induction [*cf. Rhein*, 1972, with *Preskorn et al.* 1977].

FIGURE 5.—Data on survival of mice that were fetally sham-irradiated or irradiated four times during gestation (0 or 35 mW/g for 20 min on the 11th through 14th day). The data at the point in time of 50% mortality of controls compare closely with those of Prausnitz and Süsskind (Figure 3) [from *Preskorn et al.*, 1977].









GROUP	n	AVERAGE DURATION of FIRST STAGE (min)			AVERAGE DOSE of SEDATION* REQUIRED (mg)
		LATENT PHASE	ACTIVE PHASE	TOTAL	
MICROWAVE TREATMENT					
PRIMIPARA	399	310	175	485	125
MULTIPARA	601	190	68	258	100
CONTROLS					
PRIMIPARA	385	401	192	593	192
MULTIPARA	615	225	76	301	161

*Meperidine

Prehearing Questions for IEEE and Responses

Question 1. Please review your current programs and identify for the Committee the issues which you perceive are in need of resolution. This discussion may include those issues which appear to be of immediate consumer concern, or those issues which are relevant to a clarification of federal agency responsibility. They may include your views as to needed revisions in existing legislation, initiation of research, education and training, state and federal cooperation, transportation, materials handling, disaster response, inspection or certification of devices or radio isotopes, or other similar issues.

Question 2. What new developments in the use of electro-magnetic spectrum are under evaluation or need to be evaluated in terms of potential hazards to man or the environment? For example, what issues and problems are current or anticipated with regard to the increasing use of high voltage transmission lines, increasing use of high powered lasers in industry, engineering, or other applications?

Question 3. What general reactions do you have to the allegations of need for more data on chronic exposure to low levels of microwave radiation or magnetic fields What reactions do you have to emission exposure standards now being proposed (e.g., standards for ultra-violet radiation, infrared radiation)? What is your view as to the present safety of microwave technology used in communications or consumer products?

Question 4. What is your view as to the safety of ultra-sonic technology used in industrial processes?

Question 5. What is your view as to the safety of low-energy consumption light sources, such as fluorescent, mercury vapor, etc.?

Question 6. What is your view as to the potential biological or behavioral effects of all such products?

Question 7. What are your views as to the efficacy of existing programs to study, identify, or clarify the biological effects of the electro-magnetic radiation?

Question 8. Please describe the inter-relationships of your group with other industry groups, academic institutions, and federal and state governments.

Answer 1. The Committee on Man and Radiation (COMAR) was established in 1972 by the Institute of Electrical and Electronic Engineers (EEE) which is the leading professional society in electrical engineering with about 160,000 members worldwide. The primary purpose of COMAR is to help establish a realistic and balanced perspective towards the hazards of nonionizing electromagnetic radiation. To do this COMAR attempts to present factual information on the biological effects of non-ionizing radiation to the general public, including legislators. COMAR attempts to correct false and misleading information on this subject that appears often in the general news media.

Most of today's concern and misinformation over non-ionizing radiation relates to "microwave" radiation—a term ill-defined and often arbitrarily assigned insofar as it describes the nature of exposure hazard. Present knowledge indicates the importance of a resonant frequency range that depends on size and shape of animals. In this frequency range "microwave" properties exist with maximum field penetration and absorption. The absorption and/or penetration decrease greatly at frequencies far below or above the resonant frequency range. This range for man corresponds to the region of FM and TV broadcast while for rats or mice, common experimental animals, this resonance range is above 1 GHz.

We believe that prime areas of need include:

a. increased research on "scaling" (or extrapolation) of the results of animal research to man. This includes the refinement of biological as well as physical aspects of this "scaling" process.

b. increased research directed toward beneficial effects of non-ionizing electromagnetic energy, particularly because of the promise of new medical applications such as cancer therapy and the potential contribution of microwave heating to energy conservation and reduction of environmental pollution.

c. development of effective means for public education on the nature of electromagnetic energy; the difference between non-ionizing and ionizing "radiation," the difference between effect and hazard, and other topics which can help establish a sane realistic perspective.

Answer 2. We believe in most areas that there is a good assessment of potential hazards and adequate safety standards.

In the so-called "millimeter-wave" region of the spectrum, however, there exists an ideal opportunity to explore potential bioeffects before significant practical use is realized. Interest in this part of the spectrum has been stimulated by some recent Soviet research and some theoretical speculation on new interactions mechanisms peculiar to this part of the spectrum.

Answer 3. We support the plans for more research on effects of chronic exposure to microwave/RF fields. It is to be noted that the most prevalent energies to which the general population is subject to continuous long duration exposure derive from broadcasting sources. Therefore, it is important that animal experiments be particularly designed for appropriate scaling to man at such frequencies. In general the usefulness of chronic exposure studies in extrapolating to man depends on extensive studies of frequency dependence as well as the biologists and physical aspects of "scaling".

We believe that safety in the use of communication on consumer products which produce electromagnetic radiation is adequately controlled by governmental safety standards as well as the employment of practical safety measures. In particular, the emission standard for microwave ovens is compatible with the most conservative exposure standards including those in the U.S.S.R.

It is to be emphasized that there is no (or very little) confirmed evidence of serious human injury from "radiation" of the non-ionizing type despite many years experience with widespread uses. In particular, twenty-five years in the use of microwave diathermy has not produced any confirmed injuries due to "radiation" effects.

Some attention should, however, be given to the increased use of CB and mobile radio communications because of the closeness of these frequencies to the resonant frequencies of humans. It will be desirable to establish the degree of safety afforded by present safety measures and avoid loose speculation which might arise otherwise.

Answer 4. We are aware of no practical radiation safety problems in the use of ultrasonic technology used in industrial processes.

Answer 5. We are aware of no significant radiation problems in the consumer use of light sources other than sun lamps. We are aware of and support the regulatory efforts of the Bureau of Radiological Health aimed toward radiation safety in the use of sun lamps and large special-purpose lamps where potential ultra-violet radiation hazards are possible.

Answer 6. We believe that there is no crisis and that existing safety standards appear adequate. We believe, however, that broad-based research is desirable to increase and improve our fund of knowledge about bioeffects.

Answer 7. We believe that existing programs are making progress and should be continued but with increased emphasis on "scaling" to man, beneficial effects and public education for realistic perspective.

Answer 8. The relationship of COMAR to other groups in this field are referred to in the written text of our submitted testimony. The background for our answers to these questions is provided in more detail in this written text and its Appendices.

[The following information was subsequently received for the record:]

ANSWERS TO QUESTIONS FROM U.S. SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

(Dr. John Osepchuk, IEEE)

Question 1. During your oral testimony, you referred to a publication by Dr. Czerski and stated that the United States and the U.S.S.R. microwave standards are "essentially equivalent". Please provide citations to Dr. Czerski's paper. Please provide a more detailed discussion of why you consider the Russian and U.S. standards to be "essentially equivalent".

Answer. During my testimony I stated that the U.S. emission standard for microwave ovens is "essentially equivalent" to the exposure standards in the U.S.S.R. Furthermore, I reported that the proposed emission standard for microwave ovens in the U.S.S.R. is also "essentially equivalent".

Dr. P. Czerski of Poland has long supported this conclusion. In September, 1973, during a panel discussion at the IMPI Symposium in Loughborough, England, I made the above assertion and Dr. Czerski, who was on the panel with me, expressed his agreement. Later in June 1974 during a similar panel discussion at the IEEE-Microwave Symposium in Atlanta, Georgia, Dr. Czerski and I again expressed agreement on this point. Also in June 1974 during the 7th Rochester International Conference on Enviromental Toxicity Dr. Czerski again expressed his agreement. This is documented in the Proceedings of this conference which was published in book form during 1975. In this case his comment was made after a paper which I presented. His comment in full was: "I would like to note that we agreed already one year ago in Loughborough that the equipment performance standards in the U.S.A. for microwave ovens and the U.S.S.R. personnel exposure standard do confrom exactly and we would be only too happy to import any such ovens into Poland. They would be accepted. And this time I am extremely glad that you make such a strong case for controlling the power output of broadcasting and TV stations.'

The reference for this is: S. Michaelson et al., editors, "Fundamental and Applied Aspects of Nonionizing Radiation," p. 432, Plenum Press, N.Y. (1975).

Dr. Czerski expanded on this point in a recent book which he coauthored. The pertinent remarks and references are:

"A voluminous literature on microwave ovens and the prevention of the nonintended radiation hazards involved exists [266, 267, 422, 494, 503, 550, 568]; (see also current numbers of Electronics, Journal of Microwave Power, and Proceedings of the IEEE). From the point of view of this survey, only the permissible level of radiation (leakage) is pertinent. According to the U.S. rules [422], the mean power density level at a distance of 5 cm cannot exceed at any point 1 mW/cm^2 at the moment when a new microwave oven is sold. During use this value may augment to 5 mW/cm^2. According to official statements, this value is consistent with actual knowledge on the biological effects of microwaves and may be considered as safe (Environmental Control Administration, U.S. Public Health Service). Evaluating this statement, and keeping in mind the fact that the value of 5 mW/cm^2 cannot be exceeded at a distance of 5 cm, it may be easily calculated that this is in good accord with the order of magnitude of safe exposure levels for the general population in the USSR and Poland.

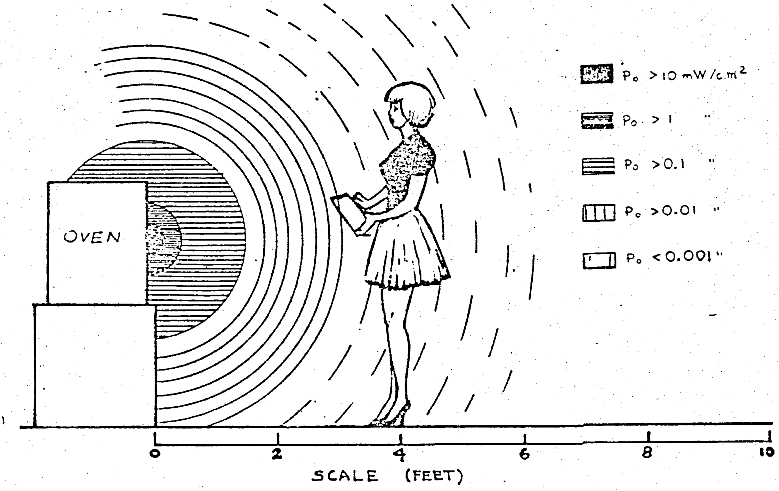
"Emission standards limiting nonintended radiation leakage should ideally tend to eliminate any such radiation. This may be, impracticable, however, from the technical or economic point at the present time. The tendency to eliminate all nonintended radiation is reflected in the U.S. Department of Health, Education, and Welfare standard concerning microwave ovens. This standard specifies that before first-user purchase the maximum permissible leakage is 1 mW/cm^2 at a distance of 5 cm. With use, this leakage may increase to 5 mW/cm^2 at the same distance. The standard specifies additionally what safety devices should be introduced to ensure compliance with these emission values. The resulting exposure was analyzed by J. M. Osepchuk, R. A. Foerstner, and D. R. McConnell in a paper, (Computation of Personnel Exposure in Microwave Leakage Fields and Comparison with Personnel Exposure Standards), presented during the International Microwave Power Institute Symposium at Loughborough, Sept. 10–14, 1973. The data presented by these authors indicate that microwave ovens which conform to this standard are a source of exposures within the USSR safe exposure limits."

The reference for this is: S. Baranski and P. Czerski, *Biological Effects of Microwaves*, p. 183 and p. 186, Dowden, Hutchinson, and Ross, Inc., Stroudsburg, Pa. (1977).

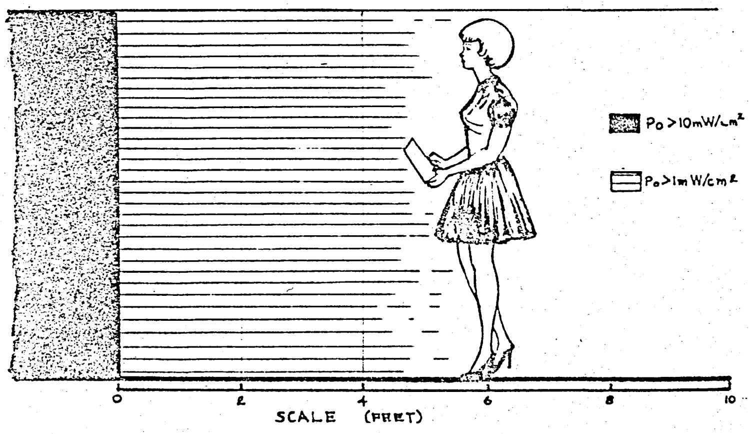
To understand why the oven emission standard is essentially equivalent to the U.S.S.R. exposure standard, consider the figure reproduced on the next page from the Journal of Microwave Power.

In the lower figure we see a person immersed in a rather uniform "far-field" of microwave radiation, as might happen at some distance from a high-power radar for example. In this case the body of the person is completely exposed—i.e., whole-body exposure. This is the situation for which exposure standards are devised. The exposure standard states the maximum whole-body flux of field or power density to which a person should permit himself to undergo exposure as a function of exposure duration.

JOURNAL OF MICROWAVE POWER, 10(4), 1975



SPATIAL DISTRIBUTION OF WORST-CASE LEAKAGE OF FIELDS FROM MICROWAVE OVEN



SPATIAL DISTRIBUTION IN VICINITY OF HAZARD AREA OF RADAR BEAM (NON-SCANNED)

The emission standard, on the other hand, applies to an equipment and not to a person. The emission standard states the maximum permissible flux or power density that is permitted at some distance from the equipment. In the case of the U.S. oven standard (HEW) the specified limits are 1 mW/cm^2 when new, and 5 mW/cm^2 in the field when measured 5 cm from any point on the external surface of the oven. Now it is a demonstrable fact that microwave oven leakage arises from small localized regions. (See for example the paper co-authored by me which is cited by Dr. Czerski above.) Therefore the radiation leakage level decreases rapidly as the radiation spreads out from a small source as depicted in the upper figure. Many data have confirmed this rapid decrease of leakage level near microwave ovens and also have shown that the decrease is approximately "inverse-square law"—i.e., the power density decreases by a factor of 4 (2^2) as the distance from the oven is doubled. Thus the level at a distance of 50 cm is approximately 100, (50 cm/5cm)^2, times smaller than the level at 5 cm. The level at 5 cm is the emission level but this is a rather arbitrary measure of the leakage. If we specified the measurement point at 1 cm the level would be much higher; if we specified it at 50 cm, it would be a much lower level. Also, of course, the area of the radiation is small at 5 cm and only at several feet does it approach a whole-body exposure.

To further understand the difference between emission and exposure consider a lit match or a small light bulb. Very close to these sources there exists an intense flux of light and heat (infrared) radiation. Still we know that at several feet the intensity is rather trivial. Our bodies are not exposed to the intensity very close to the source but to that much reduced intensity further away. Similarly, the measure of exposure near a microwave oven is that flux level which the body intercepts taken together with the duration of the exposure. Studies of what this likely integrated exposure is for persons operating microwave ovens have shown that the exposures are well below U.S.S.R. limits even if the oven leaks at the emission limit. (See, for example the paper co-authored by me cited by Dr. Czerski above.)

The soundness of this fundamental physical reasoning has been recognized by Dr. Czerski and most scientists involved in this field.

Question 2. During your oral testimony, you stated that microwaves at any level are not dangerous. Please clarify for us whether this is your personal opinion or whether it represents the position of the IEEE Committee on Man and Radiation.

Answer. The statement attributed to me in the question is an obvious misquotation since everybody knows, that at sufficiently high levels or intensities of power anything is dangerous. What I did say when discussing COMAR's response to fears of microwave relay towers was: "COMAR pointed out that ground levels of radiation from the tower would be several orders of magnitude below even the U.S.S.R. exposure standard, that thousands of such towers already exist without evidence of radiation hazard, and that fears of 'microwaves' at any level were irrational". The last phase when isolated is admittedly ambiguous but in the context when presented clearly refers to fears of the entity "microwaves" regardless how low the level. COMAR has consistently stated that "microwaves" should not be feared but that high-intensity microwaves which could approach damage levels are to be feared. An appropriate analogy is that we don't fear "voltage" per se but only "high voltage"—otherwise we would not handle flashlight batteries so freely.

In response to a question by Senator Stevenson I made the same clarification. The statement, as clarified, certainly represents the position of the entire COMAR committee.

Question 3. During the course of your testimony you referred to the dispute on proposed emission standards on microwave diathermy machines. Please provide a clear statement of the issues involved in this dispute and IEEE's position on the issue.

Answer. Microwave diathermy is the process of heating a portion of the human body by means of irradiation of that portion with power up to 100 watts for periods typically up to 30 minutes. The type of equipment used has essentially been the same for 25 years. It operates at 2450 MHz and uses an applicator generally spaced from the body by 2–4 inches to direct the energy into the desired location of the body. Although the predominant share of the energy goes into the desired location there is always some stray radiation, some of which impinges on the body at distant points from the treatment area and some of which is radiated into the surroundings in a diffuse manner. Despite the existence of the low-level stray radiation it is the contention of medical users that the equipment has been safely used for the last quarter century. In 1973 Professor Lehman (University of Washington), a leader in physical medicine stated: "Use of these modalities according to prescribed indications and contraindications has produced no proven or documented incidence of irreversible damage to any biologic tissues to which the modality is applied or which may be incidentally exposed".

The reference for this is: Hearings before the Committee on Commerce, U.S. Senate on Public Law 90-602, March 8-12, 1973, Government Publication No. 93-24, pp. 462-463.

The stated purpose of the diathermy standard proposed by the Bureau of Radiological Health (BRH) is to minimize stray radiation in microwave diathermy by restricting the emission from the diathermy applicator to only the treatment area in a more stringent way than in present equipment. In other words, the proposed standard is an emission standard and not an exposure standard. It restricts the possible designs of applicators only to those which when applied to certain standard phantoms do not leak more than 5 mW/cm^2 when measured at 5 cm from the equipment or applicator. BRH has demonstrated an applicator design which does this. BRH has not shown that this design or any other will exhibit less than 5 mW/cm^2 when applied to arbitrary locations of the human body and when measured near the body and not just at the applicator.

The standard has been opposed by medical users, industry and COMAR for several reasons.

(a) BRH has not demonstrated its need for safety and health—i.e., previous and existing diathermy practice has been deemed safe by authorities such as Professor Lehman.

(b) The standard is impractical. It specifies leakage when phantom tests are made but does not control leakage in the wide variety of practical uses on real human bodies.

(c) The standard restricts design and also medical practice—e.g., essentially requiring contact applicators which would interfere with desire for ventilation or visibility of treated area by a physician.

(d) The standard, if adopted, would force the one U.S. manufacturer to cease production of the equipment because of the increased costs and potential liability implicit in the application of an overly restrictive standard in the medical area.

COMAR has presented its opposition in testimony before the Technical Electronic Products Radiation Safety Standards Committee (TEPRSSC) and by letter to BRH. In the latter Dr. Ecker, Chairman of Comar, stated:

"As a basic premise, COMAR believes that unnecessary restrictions on the use of a beneficial tool by qualified practitioners is undesirable. Setting a limit on the power density that can be emitted from microwave diathermy equipment could unnecessarily restrict the benefit that could be derived from various types of diathermy treatment. The question of limits should concern only the power density impinging on portions of the body that are not to be heated and on equipment operators after appropriate screening and shielding procedures.

It would be better to regulate more carefully the qualifications of diathermy operators than to limit drastically the flexibility of the equipment. Microwave radiation is becoming more widely used in a variety of medical and biological applications in addition to diathermy per se. With proper design for flexibility, one microwave power source in a medical installation could perform many useful functions. Unnecessary restrictions that prevent such flexibility should not be imposed upon equipment manufacturers.

Based on our information on the subject of microwave diathermy usage; the proposed standard appears to be unnecessary and could seriously hamper the beneficial applications of microwave radiation in biology and medicine.

Question 4. During your testimony you stated that if important low-level non-thermal effects did exist, they surely would be exploited by the medical profession and the industry. Does this statement imply that you do not feel that research into non-thermal effects of non-ionizing radiation is justified?

Answer. Despite the considerable research on microwave bioeffects the only demonstrated principles of interaction on living tissue relevant to hazard or beneficial effects are thermal—i.e., producing biologically significant temperature rise in some tissue. (The microwave "auditory" effect involves the excitation of audible acoustic energy in tissue by the thermo-elastic conversion produced by the fast temperature rise and consequent differential expansions produced by intense narrow (i.e., microseconds) pulses of microwave radiation. It has not been relevant to practical hazards since the only common source of pulsed microwave radiation is radar and the typical radar operating parameters (e.g., duty cycle) generally are such that the auditory effect can occur only with a concomitant significant average temperature rise—i.e., thermally significant average levels of radiation.) This viewpoint is consistent with the HEW position that the only valid basis for therapeutic effects from diathermy is the presence of significant heating.

The absence of evidence for biologically significant non-thermal effects does not mean that speculations on research entertaining non-thermal effects are not justified, per se. Certainly if new theory or experimental evidence suggesting non-thermal effects are discovered, they should be pursued. One can be justifiably skeptical about loose speculation about non-thermal effects, however. Since the turn of the century there have been frequent claims of discovery of such effects. So far they have all been proven false and it is reasonable to restate the position of the medical profession in 1942, viz. "the burden of proof still lies on those who claim any biologic actions of these currents other than heat" (W. Bierman, The Medical Applications of the Short-Wave Current, Williams and Wilkins Co., Baltimore (1942), p. 114.

As time goes on the elusive "non-thermal" effect of biological significance increasingly assumes the aspects of the generally discredited goal of "perpetual motion" which tantalized earlier generations of scientists in history. Thus it is inconceivable that useful medical applications would not follow the true discovery of "non-thermal" effect. So far the medical profession and support industries have not been presented this discovery.

Question 5. During the course of the hearings several other witnesses from federal scientific establishments exhibited considerable uncertainty with respect to the existence of non-thermal effects. Please comment.

Answer. I agree with the use of the word "uncertainty" with respect to the existence of non-thermal effects characterizing testimony of other witnesses. I feel confident that they would agree that only when research results display a convincing degree of "certainty" can they be said to be scientifically accepted. It is important to remember that practical decisions can be made only on what is known (scientifically) and not on what is not known.

The "uncertainty" is believed to arise whenever reports of significant biological effects at low-levels is reported—sometimes with some evidence of no significant temperature rise in experimental animals. One can note, however, that in the past some reports in this category have been later downgraded either by failure to replicate, discovery of artifacts, or errors in dosimetry. Experience supports a viewpoint of skepticism in assessing new reports of this type.

It is my opinion that in some cases involving radiation of small animals that some effects may be thermal despite apparent absence of temperature increase. Usually only core or rectal temperature is monitored whereas with radiation at "low" levels of a few mW/cm^2, and frequency between 0.5 and 10 GHz, it is conceivable that "hot spots" occur in experimental animals with only localized temperature rise. For technical reasons it is doubtful that such subtle thermal effects will "scale" to the human case, however.

It is certainly desirable to pursue research in these studies to a stage of more certain understanding. The payoff relates not only to a more exact assessment of biological hazards but also potentially to improved medical applications and also industrial applications involving complicated microwave heating distributions.

Question 6. Does COMAR have evidence that people have been harmed in any way through the use of microwave ovens?

Answer. To my knowledge no evidence of injury to people using microwave ovens has been presented to COMAR where such injury was caused by the microwave energy. We are aware of only one officially recorded case of injury in the NEISS system operated by the Bureau of Product Safety. This was a case where a young boy suffered a laceration on the head when his mother inadvertently pulled the door down onto the boy's head.

We are aware of claims of injury but have seen no evidence that these claims are valid.

Question 7. Have any legal suits been filed against microwave oven manufacturers, claiming damage from the use of such ovens?

Answer. We have been aware of several suits against microwave oven manufacturers. We are aware of no such case that resulted in a judgment against the manufacturer. We are aware of several cases in which the judgment was in favor of the manufacturer either by jury verdict, directed verdict or dismissal of complaint.

Question 8. Is every microwave oven tested before it is released for sale to the public? What is the nature of that testing?

Answer. COMAR cannot authoritatively speak for the microwave oven industry. We suggest the question be placed to the Association of Home Appliance Manufacturers.

It is our understanding, however, that each microwave oven is tested to insure that it meets all BRH regulations on leakage limits with a standard (275 ml) water load and satisfactory operation of the interlock system which shuts off the microwave power when the door is opened.

Question 9. Is data being accumulated on the in-use experience of microwave equipment? How are we certain that such equipment is staying within operating specifications?

Answer. I presume the question is addressed to operating parameters related to "leakage" and safety and not performance unrelated to safety.

We are aware that both industry and BRH conduct extensive life test and field surveys of microwave ovens. Generally speaking the results indicate that BRH leakage limits are being met with great assurance in the field.

We are also aware of similar experience with microwave industrial-heating equipment. More detailed information in this field could be obtained by contacting the International Microwave Power Institute.

Question 10. In your prepared comments, you state with respect to microwave ovens that ". . . the U.S. emission standard is accepted world wide". Please amplify this statement and provide documentation for the record.

Answer. Since its inception the U.S. emission standard on microwave ovens in equivalent or close approximation has been increasingly accepted as an adequate safety standard for microwave leakage radiation compatible with any exposure standard in the world. Steps in this acceptance include:

(*a*) A description of a standard for microwave ovens in Czechoslovakia by Dr. K. Marha in 1969 which was similar though expressed differently. The Czech standard applied to microwave oven manufacturing labor personnel and specified integrated-dose limits of $200\mu W/cm^2$ hours for each 8-hour working day as measured 25 cm in front of the oven at two heights corresponding to position of eyes and gonads.

Reference for this is: K. Marha, "Maximum Admissible Values of HF and UHF Electromagnetic Radiation at Work Places in Czechoslovakia," Proceedings of the Symposium on "Biological Effects and Health Implications of Microwaves" HEW Document BRH/DBE 70.2 (1970), p. 194.

(*b*) Canada adopted a leakage limit of 1 mW/cm^2 at 5 cm from the external surface of the oven with the specified minimum load in the oven.

(*c*) The International Electrochemical Commission has adopted a microwave oven leakage standard of 5 mW/cm^2 at 5 cm from a microwave oven. This was approved by representatives of many countries, including those in the U.S.S.R.

(*d*) As stated earlier, Dr. P. Czerski of Poland has stated that the U.S. oven standard is fully compatible with exposure standards in Eastern Europe.

(*e*) Recently an emission standard for microwave ovens has been proposed in the Ministry of Public Health in the U.S.S.R. This specifies 10 $\mu W/cm^2$ measured 50 cm in front of the door. This is equivalent to the U.S. limit of 1 mW/cm^2 at 5 cm by virtue of the inverse-square law (Personal communication of writer with Dr. J. D. Dumansky and Dr. Los at the 1977 IMPI Symposium ŏn Microwave Power, Minneapolis, Minn., May 27, 1977).

(*f*) A similar standard for leakage from industrial equipment of 10 mW/cm^2 at 5 cm from such equipment has been adopted by the International Microwave Power Institute with approval by members throughout the world.

Question 11. Please describe the circumstances surrounding the recent recall of 36,845 General Electric microwave ovens which the Bureau of Radiological Health found to be leaking radiation ". . . in excess of the limit permitted by the Federal Performance Standard." What subsequent actions has General Electric taken to ensure that these ovens will comply with the standard before sale to the public, and to improve manufacturinog procedures for other microwave ovens?

Answer. COMAR cannot speak for General Electric who should be contacted for information relative to this question.

As an individual I can point out, however, that radiation in excess of the BRH limit is not per se hazardous. It should be remembered that a very large safety factor is implicit in the standard. The great value of this safety factor is reflected in the fact that the emission standard is compatible with the conservative U.S.S.R. exposure standards. Also a committee of the American Medical Association has stated that the typical safety factor is of the order of 10,000 (AMA Committee on Occupational Toxicology, Editorial, "Microwave Ovens," J. Amer. Med. Assoc. 215, No. 10, pp. 1661–1662, (March 8, 1971).)

Question 12. How do you assess the many Soviet studies which have reported a whole range of symptoms in people chronically exposed to low level microwaves? In your opinion, what is the explanation for the fact that Western studies are not producing the same results? Will closer work with Soviet researchers enable us to clarify this problem?

Answer. Soviet papers reporting evidence of chronic effects in people exposed to low-level microwaves have been skeptically received in the West because of questionable statistical reasoning, methods of gathering data and other questionable techniques (S. Michaelson and C. Dodge, "Soviet Views on Biologic Effects of Microwaves: An Analysis," Health Physics 21, pp. 108–111 (1971)). In fact even some more recent publications by those in Eastern Europe seem to implicitly criticize the previous reports. For example, one study of military personnel in Poland has shown no correlation of microwave exposure and eye damage (P. Czerski et al., "Health Surveillance of Personnel Occupationally Exposed to Microwaves," Aerospace Medicine 45, pp. 1137–1148 (1974).)

A recent Soviet paper indicates that previous reports associating cardiological problems with microwave exposure are in error because other health factors were not recognized (A. R. Gus'kova and Y. M. Kochanova, "Some Aspects of Etiological Diagnostics of Occupational Diseases as Related to the Effects of Microwave Radiation," Gigiyena Truda i Professional'nyye Zaboleraniya, No. 3, 1976).

I feel confident that further studies both in the United States and U.S.S.R. will help produce more agreement in results. Cooperation between researchers in the two countries will be invaluable in this process.

Senator STEVENSON. Our final witness is Dr. Russell H. Morgan of the American College of Radiology.

STATEMENT OF DR. RUSSELL H. MORGAN, AMERICAN COLLEGE OF RADIOLOGY, CHEVY CHASE, MD.

Dr. MORGAN. The following testimony is presented at the committee's request on behalf of the 14,000 physician and physicist members of the American College of Radiology. We appreciate the opportunity to contribute our views to public policy considerations of medical X-ray exposures.

I am Dr. Russell H. Morgan of Baltimore. Accompanying me are Dr. Harold O. Wyckoff of Washington, and Otha W. Linton, director of government relations for the American College of Radiology.

In our opinion, the Nation's public and private controls and guidelines for medical and other uses of ionizing radiation are in relatively good order and working well. There are no absolutes. Problems remain in both the private and public sectors. But taken on the whole, Americans are not being subjected to grossly improper radiation practices or excessive levels of exposures.

In our background material, we noted three areas of current concern with Federal postures for radiologists and others working with medical radiation. They are:

1. Absence of a focus for radiation-related research within the Federal Government.
2. An overlapping and sometimes contradictory pattern of regulatory effects by Federal and State agencies in the health field and elsewhere in Government.

3. An emphasis on health costs containment which seems likely to stifle further development in radiation equipment.

To put the three points into the context of the opening remarks, a bit of background would be helpful. The assertion that medical uses of ionizing radiation are in good order is based upon the recognition of a substantial and continuing effort by a lot of people in and out of Government.

It has been said that medical radiation accounts for more than 90 percent of all manmade ionizing radiation received by Americans. While the fraction may be inexact, it reflects a circumstance which is greatly beneficial to the country.

Perhaps three of every five Americans receives an X-ray examination in any year. Each of those examinations is made on the basis of a medical decision limited to one part of the body, the area of clinical interest, whatever it may be. It might be a finger or toe, the head, the arm, or abdomen. At least two of every five examinations are of the chest. When scaled out into numbers, the contribution of this medical radiation to the absorbed radiation received by the population as a whole is about the same as that received from natural sources.

When we state that in numbers, we talk of the national annual average of background radiation from the soil, the air, our food, and body substances as approximating 80 millirads with medical radiation estimated as 60 to 100 millirads for the population as a whole.

Of course, certain individuals receive much more, particularly those receiving radiation treatment for cancers.

The question then turns to the effect of adding this medical exposure to the exposure which all of us receive from natural background sources. Most medical X–ray examinations contribute less than 1 rad—1,000 millirads—or 12 times annual background radiation, to the body part being studied. A few may contribute 2 or 3 rads.

At those levels, there have not been any directly observable biological effects.

However, we know that there are biologically harmful effects from X–ray exposures at higher levels. Certainly we can observe effects at 100 rads and some types of effects at only 25 rads in a large enough study group. Below that, we must resort to indirect methods of observation using epidemiological and statistical methods.

To allow some quantification of these low level exposures, radiation scientists have postulated a worst case theory called the linear nonthreshold hypotheses. Simply put, this assumes that if 100 rads on a living creature produce a given effect, then 1 rad will produce one one-hundredth part of that effect.

Because of our historic exposure to background radiation and because radiation effects such as certain diseases are found in persons having no medical X–ray exposures as well as those having X–ray examinations, the linear nonthreshold hypothesis must remain hypothetical, capable neither of absolute proof nor absolute refutation.

The National Council for Radiation Protection and Measurements has cautioned against its literal application to public policy for radiation exposure because its "worst case" assumptions almost certainly overstate the impact of low-level ionizing radiation.

The linear, nonthreshold hypothesis also assumes that all radiation doses are cumulative and that the body has no recuperative factor from radiation injury. We know that such an assumption is not correct in any literal sense. As with any other injury, a large total body radiation dose received in a single exposure or shortly spaced exposures can be lethal. The same amount of radiation over a lifetime may produce only statistically observable effects.

The currently accepted radiation therapy for many forms of cancer cells for delivering 5,000 to 7,000 rads of radiation to the tumorous tissues to destroy them. Every effort is made to deliver lethal radiation to the entire tumor and to spare surrounding tissues to the greatest possible extent.

Patients do live normal lifespans with no recurrence of cancer after successful radiation treatment early in life. They do bear normal children after radiation therapy even in the vicinity of their reproductive organs.

There would appear to be a substantial margin of safety for the exposure of individuals to carefully planned and performed medical X-ray exposures of selected body parts. But what about the exposure accumulating in the population and in the population's genetic pool? We make the further reasonable assumption that any mutation introduced into the genetic substance of the human race is likely to be deleterious.

We know that radiation may have an effect upon genetic materials at doses which show no effect upon the person receiving the exposure. Radiologists and other physicians have been particularly alert to medical exposures of the reproductive organs, particularly of women of childbearing age and potential.

There are two types of studies of radiation-induced genetic effects. One is the animal studies of mice or other animals where much higher than diagnostic doses are used to get a measurable effect. The other group is the retrospective epidemiological studies of groups of humans who have received X-ray exposures under certain conditions. Both types are fraught with uncertainties, however carefully done and however conservatively extrapolated.

The tradeoff of medical radiation benefits against risks can be seen to be generally favorable. If a properly selected X-ray examination is properly performed, the diagnostic information greatly outweighs the theoretical or statistical risk. This is true even when the patient may have a special circumstance, such as pregnancy, if the clinical question raised by her physician is not answerable by other diagnostic methods.

However, the favorable balance is not automatic. It must be sustained by constant attention to good patient selection and to proper technique with safe X-ray equipment. This combination will allow the attainment of benefits with "as low as practicable" exposures. As X-ray techniques and equipment have improved, the levels of "as low as practicable" have decreased enough essentially to offset the increased volume of X-ray examinations to the public. For example, gonad shielding greatly reduces genetically significant dose.

This relates to points 1 and 3 in our stated concerns. While we are aware that we cannot attain complete and absolute answers to our radiobiological questions, we must strive for better ones. The role of ionizing radiation will not diminish in modern medicine. But the amount of radiation per examination can sometimes be lowered with further attention to techniques and equipment. However, if radiological research and education are not supported and industrial development is curbed or frozen, little further progress in dose reduction can be expected to offset projected increases in X-ray usage.

A decade ago, the American College of Radiology testified before this committee in support of enactment of Public Law 90-602, the Radiation Control for Health and Safety Act of 1968. Earlier, the college had supported the creation of the Bureau of Radiological Health. We believe that there is proper role for Government in the safe and effective medical uses of X-rays. But that role is not simply a regulatory one. Equipment can be regulated. Medical judgment cannot be.

The weight of Federal activities dealing with medical uses of ionizing radiation has been regulatory. Presently, we are distressed to be the target of a rousing bureaucratic battle among Federal agencies who would regulate us in various ways. Only one, the Bureau of Radiological Health, has devoted any portion of its current program to enhancing the benefits of medical exposures.

A decade and more ago, the Atomic Energy Commission balanced its effort between promoting the use of nuclear byproducts in medicine and making certain that such uses were safe and effective. Most of that effort is now gone with the redirection of its successor agency into national energy problems.

In 1970, the college petitioned the Secretary of HEW, to make a study of the radiation-related programs within his own Department in the interest of exerting some management control.

In the intervening years, nothing happened until HEW was threatened by activities organized by EPA. EPA claimed a domain over medical radiation on the basis of its inheriting the responsibility of the Federal Radiation Council, but the eight FRC reports which set national policy in the 1960's all avoided positions on medical radiation. In addition, it seems to us that reorganization order 3, which created EPA, specifically left medical radiation to HEW and retained the major portion of the Bureau of Radiological Health within HEW to carry out Federal responsibilities. We are informed that BRH will soon take responsibility for radiology devices.

With the entire health community being accused of disregard for costs, we emphasize that duplicative and often contradictory Federal regulations are a significant contribution to the high costs of radiology service. This is particularly likely to be true of the literal application of sanctions under the 1976 medical device amendments to radiology products. The FDA's Bureau of Medical Devices and Diagnostic Products thus far has taken a position that anything used in a medical facility is a medical device to be regulated. By that token, the manufacturers of ballpoint pens, telephones and cathode ray tubes are makers of medical devices since their products are used in medical facilities. We cannot even estimate the increased costs of this attitude by a regulatory agency.

But a further question still persists about whether Americans are getting the right amount of diagnostic and therapeutic radiology services, far too many, or not enough. Various writers have suggested recently that some portion of the examinations received by Americans have no medical justification. With current malpractice problems, doctors are said to request X-ray studies for their own protection instead of the patient's medical needs.

We have no certain way to answer these questions for current practice. But we have worked to eliminate any excess. Years ago, we cooperated with the American Academy of Pediatricians to urge pediatricians to stop using fluoroscopes. We worked with the American College of Chest Physicians, the Center for Disease Control and the Bureau of Radiological Health to urge a halt to community chest X-ray surveys as a case finding method for tuberculosis. We have worked with the American College of Obstetricians and Gynecologists, the NCRP and the BRH on statements of good practice in abdominal X-ray examinations of pregnant women. In recent years, the College, the X-ray industry and the BRH have been cooperating on a dynamic program to improve the quality of X-ray practice. Every repeat film which can be avoided is a savings of radiation, money, energy, and time. The College also has been working with most of the Nation's medical schools through the production and distribution of a radiology learning laboratory which was developed jointly with BRH.

More broadly, we have been engaged in the college since 1971 in an extensive study of diagnostic radiologic efficacy. Efficacy, in the context of the study, is defined as the useful impact of information gained from the X-ray procedure upon the management of the patient who received it. To take a simple example, a possibly fractured ankle is confirmed to be broken or proved to be only sprained by an X-ray examination. The efficacy is total with either finding since it determines the treatment of the problem. Drs. Loop and Bell, in a study of skull X-ray examinations in hospital emergency rooms, suggested that the X-ray findings were of little value in the absence of clinical findings because the result failed to change the management of the patient. In most clinical situations the radiologic result is combined with other diagnostic information to reach a medical decision about treatment and the efficacy is somewhere between the total reliance in the ankle injury and unproductive results of the skull films.

The efficacy study by the college committees is an extensive prospective attempt to establish and verify criteria by which doctors and others can judge the usefulness of X-ray examinations for patients with specific sets of conditions. The task is difficult and complex. The Federal support which was forthcoming to begin the study has dwindled to a level which prejudices completion of the field portions of the study.

It seems to us in the American College of Radiology that this approach is absolutely vital. Our still incomplete study has generated much activity elsewhere within the specialty and elsewhere in medicine. All of the radiation exposure in an unneeded examination is wasted, however careful the technique. Yet, physicians are trained to err, if at all, on the side of doing too much rather than too little to make a diagnosis and treat their patients. It will not be enough to convince radiologists that certain examinations are not indicated in certain circumstances. The evidence must be clear and convincing to surgeons, internists, professional standards review organizations and hospital staffs. Only then will the patterns imprinted on young doctors change.

In the past decade, the numbers of young physicians electing the specialty of radiology has almost tripled the numbers of radiologists.

The geographic distribution is reasonably good, as indicated by an ACR study. The number of specialists in radiation therapy is still far short of national needs by every estimate. On the diagnostic side, it was possible for the ACR 4 years ago to suggest that the Nation might be nearing parity between the supply of radiologic specialists and national demands for radiologic services. A more recent study now suggests a slippage. This slippage may be the result of medical and governmental emphasis upon channeling a greater portion of young physicians into primary care disciplines. We would caution that primary care physicians are taught to understand and appreciate the role of radiology but not to perform adequately as radiologists. Thus, allowing for a more sophisticated use of radiology by these new doctors, we envision a continuing need for our services at current levels or more. With new techniques, new equipment, and new understanding, our contributions will maintain their importance in modern medicine.

The state of American medical radiation is generally good. Demands upon radiology are growing. We will need Government help and support to achieve and maintain excellence. We have Federal attention, though much of it is misdirected.

Our plea is that this Government attention be more productive, less competitive, and less costly to all of us.

Senator STEVENSON. Thank you, Dr. Morgan.

In responding to committee questions, you clarified current medical policy in recommended minimum dosages, stating there are none and that a radiologist uses as low as practicable doses.

Illinois has recommended maximum dosages for certain medical examinations.

Would you comment on the experience of radiologists under such a system?

Dr. MORGAN. Well, Mr. Chairman, the position of radiologists, I think, historically over the years has been to reduce radiation exposure just as much as possible. And I think the record is rather clear over the years that a good deal has been accomplished in this area.

The issue of maximum exposure is an interesting one. It does, however, imply some restriction on the freedom of a physician to pursue the diagnosis of a particular patient. And I would hate, myself, to be a patient undergoing diagnostic study for whom, even at the end of as much exposure as has been conducted the problems have not been resolved, yet nothing more could be administered because the maximum limit had been reached.

So I think this is a difficult area to get into. And I would be worried about it.

Senator Stevenson. You say that at a two to three rad level there are no directly observable biological effects.

Can you give us your reaction to Dr. Bross' statement to the contrary?

Dr. MORGAN. Well, I think I would answer Dr. Bross in several ways.

First of all, What Dr. Bross said would indicate that the whole issue of the biological effects is at the level of one rad is now clear, and we could go on basing our future policy on the basis of that.

It just so happens—and I would like to cite for the record a paper by P. G. Smith and M. C. Pike of the Department of Health and Social Security of the Cancer Epidemiological and Clinical Trials Unit of the University of Oxford, and L. D. Hamilton of St. Catherine's College, also of the University of Oxford, which raises serious questions with some of the premises and assumptions which Dr. Bross has made.

I don't want to go into this in any detail at the moment since it is a complicated statistical issue, and so I will leave it at that, with the introduction of this material.

But I think as a general summary of my remarks to Dr. Bross' comment, I think that really nothing has changed as far as our understanding of the relationship between dose and biological effect contrary to some of the comments which he has made.

Radiologists are very, very much aware of the hazards of radiation and these relationships between dose and biological effect.

Indeed, radiologists were first alerted to this as far back as the early 1900's when they began because they had no other way of knowing, running into problems with radiation—radiation exposures as a result of testing their equipment each morning by seeing how well their hands appeared on the screen.

As you know, a lot of the radiologists at that time received a good deal of injury.

Going on to a later time, it was radiologists helped by physicists in the 1950's who became very, very concerned with the public health services, and HEW were literally doing nothing about the problems of radiation exposure and radiation hazards associated with them, and as a consequence of this ultimately developed what we now know as the Bureau of Radiological Health.

But this was all something that was generated not by a so-called ignorant group of radiologists who would not respond to the facts that the scientists had pointed out, but quite the contrary. This was something that had been generated by radiologists who, being knowledgeable of the problems over a number of years, saw the need to do something about radiation control.

Senator STEVENSON. You said that diagnostic information greatly outweighs the statistical risk.

If a proper examination was performed—that statement assumed good equipment, competent operators, and a necessary exam.

We have heard testimony indicating that we can't assume that those conditions are always met. What is your reaction to those comments, those three assumptions? First, the equipment. Is it properly maintained? If not, what should be done?

Let's start with the first.

Dr. MORGAN. OK.

Well, there is, of course, now the legislation which has been passed by Congress which calls upon the Bureau of Radiological Health to establish equipment standards which go a long way toward assuring the public that the radiation equipment used is free from significant danger.

Of course, the question arises, what happens after the Bureau of Radiological Health's inspection and action taken in regard to new equipment is put in the field and is then used either wisely or unwisely?

Well, the problem here, I think, boils down to two parts: who is making sure that the equipment is being maintained properly, and who is assuring that the equipment is being used properly?

Now, as far as the maintenance is concerned, this function has been largely left to the States and has been pointed out by others. This tends to be rather spotty.

On the other hand, one should not forget that certainly in most of the large hospitals of this country there are very knowledgeable staffs of physicists who are not riding herd on maintenance problems every 6 months or every year or every 2 years, but are doing it continuously on a day-to-day basis.

And hence, I think that we can be reasonably reassured that there are not any gross redirections of what is—what you and I would call good maintenance in those institutions.

Now, of course, there's a good many others that are not so fortunate for which we have to be concerned.

As far as the use of the X-ray equipment is concerned, there has been some discussion here before today about how do you deal with the problem of the training of X-ray technicians who use this equipment in day-to-day use. And the issue has been raised, don't you need some sort of regulatory authority based upon some examination process, perhaps, that assures that every X-ray technician is going to do a good job.

Well, I would like to make a couple of comments on this.

One is that there currently is a rather large organized effort to assure that a large number of technologists are well trained.

For instance, the Council on Medical Accreditation—or the Council on Medical Education, the Committee on Accreditation of the American Medical Association, reviews the training programs of a large number of institutions throughout this country who are training X-ray technicians.

And the American Society of Radiological Technologists has periodic examinations where individual technologists are given an accreditation as a result of passing that examination.

Now, the College of Radiology has been very much involved in this development and has a number of studies going on to see what the effectiveness of this kind of program is.

Now, there are 107,000 X-ray technologists who have passed this examination. It has been estimated that perhaps there are about 70,000 more who have not. And the question is raised as to whether or not some regulatory action is needed for these people. I am not sure about this. And for this reason—the issue of breast radiography came up here this morning. And I can say that all of the technologists who have been involved in the breast program are qualified people.

And I suspect that most of the hospitals throughout this country, most of the doctors' offices who do a significant amount of radiography are using registered technologists who have gone through an approved training program and have passed the examination that I just referred to.

It is for that reason that we are not too impressed about the arguments one way or the other on this issue.

But perhaps there is something to look at here. I think that perhaps the colleges have studies on this, getting quantitative data on just what the magnitude of the problem is, could be helpful regarding future legislation.

Senator STEVENSON. Did you say the funding for that study has been reduced?

Dr. MORGAN. That is another study that you are referring to. The study which is reviewing the efficacy of X-ray examinations is essentially a quality control study that looks at the professional usefulness of various X-ray procedures.

For instance, the matter of getting back to this breast business here, the question was raised as to the efficacy of mammography in the diagnosis of breast cancer.

If you extend that issue to all of radiology, this is a very important thing to do, and the college has begun such a study. Because of shortages of funds within the Federal Government, some of the support for that looks as though it may taper off. But I think that the college will do everything, make every effort to continue it, because it is such an issue in the whole business of this matter, no only of radiation dose and medical benefits but also in such matters as the cost of health care.

One of the things which is not generalized at the present time because radiology has grown so rapidly since the X-ray was discovered a little over 80 years ago, is that within that time radiology today sits right at the central crossroads of the health care system.

And one—and as you look at the cost of health care, you had better start right off getting the issue of radiological cost and usefulness studied right from the beginning.

Senator STEVENSON. That study will be responsive to the third part of my question about the necessity for all of the examinations. The claim has been made that people are receiving many more X-rays than they need.

Do you have any response to that claim at the moment?

Dr. MORGAN. Well, without quantitative information generated from studies of this sort, it is very difficult to come up with answers to that particular question.

My own reaction is perhaps best given by a personal experience of my daughter, who is 30 years younger than I am, and who a couple of years ago developed a lump in her breast. She called me up and wanted to know what to do. She happened to be working at the Massachusetts General Hospital. She is not a physician. And I advised her to go to the University Health Services and let them follow it from there, and they did. They confirmed what she discovered. And then she went on to have an X-ray taken and then a surgical removal. Fortunately, it turned out to be benign, benign fibrocystic.

Well, anybody who knows anything about this knows that this sort of business recurs over and over again, and many women have it. And sure enough, a couple of years later it recurred, a couple months ago, and again what do you do about it?

She is as much, incidentally, radiation concerned as almost anybody I have run into, and she wanted to know whether she should have another X-ray. Isn't palpation good enough? Well, I think that if there were not any possibility in sight of reducing the radiation exposures of mammography over the next 5, 10, 15 years, or the rest of our lifetime, I think that she raised a very good question.

But fortunately, there are some new developments on the scene which are going to substantially reduce breast exposures, not from exposures of the past, 5 to 10 rads, and a few years later down to 1 rad. The new techniques look as though they will reduce it to something of the order of a tenth to a fifth of a rad.

On the basis of this I said go ahead. And she did. And the X-ray showed that it was more of the same that she had before. And the surgeon, instead of removing it this time, put a needle into it, removed the fluid that was suspected and that was that.

So it is very difficult to answer the questions of what we should do next because there are so many problems, so many interrelations that we are dealing with here. There is the efficacy of the process which is unknown, there is a changing radiation dose problem which the whole technological industry has been trying to reduce.

And I think that although it is not possible to answer your question directly, it is possible to say that this is something which we are proceeding with very carefully.

Senator STEVENSON. When will those two studies be completed?

Dr. MORGAN. I will have to turn for an answer to Mr. Linton who is administering and running that program for the college.

Mr. LINTON. The efficacy study may not be completed as long as medical diagnosis is necessary. But we are learning as we go along, and we are about ready to report some of the preliminary reports.

In saying that some X-rays are unneeded, the question is which ones. And we hope to be able to tell you that.

Senator STEVENSON. Soon?

Mr. LINTON. Yes, sir, soon.

Dr. MORGAN. Mr. Chairman, I think it will be fairly clear that this is a continuing problem.

Senator STEVENSON. Yes.

Dr. MORGAN. You develop new technologies, not necessarily radiological ones, but which involve radiology which start the process all over again.

Senator STEVENSON. Dr. Morgan, I am afraid I have run out of time. This has been very helpful to us.

But we have a few more questions. I would like, therefore, if I might, to follow up in writing.

Thank you very much.

Dr. MORGAN. Very good.

Thank you, Senator.

PREHEARING QUESTIONS OF THE COMMITTEE AND THE AMERICAN COLLEGE OF RADIOLOGY RESPONSES

Question 1. Please review your current programs and identify for the committee the issues you perceive are in need of resolution. This discussion may include those issues which appear to be of immediate consumer concern or those issues which are relevant to a clarification of federal agency responsibility. They may include your views as to needed revisions in existing legislation, initiation of research, education and training, state and federal cooperation, transportation, materials handling, disaster response, inspection or certification of devices and other similar issues.

Answer. To understand the context of the College's views on the several subjects noted above, a few comments about its scope and mission are helpful. The ACR is a membership organization representing most of the nation's medical specialists in radiology and also many of its radiation physicists. Radiologists in their offices and hospital x-ray departments are responsible for about two-thirds of the x-ray procedures received by Americans each year. Modern radiology is devided into two major segments, diagnosis and therapy. The largest number of radiologists are diagnosticians, working by referral as consultants to other physicians. They perform and interpret examinations using x-rays, radioisotopes, ultrasound and thermographic emissions, and other forms of radiation. The second group of radiologists, therapists, use high energy radiation in the treatment of disease, mostly cancers.

The ACR has existed in its present format since 1935. During that time, it has expanded to embrace responsibilities in radiologic education, manpower, equipment, radiation safety, public health, standards of practice, health economics, cancer detection and treatment, occupational health and public relations. The College is not a direct provider of health services. Its ideas and projects are executed by committees and staff and are adopted on their merits by radiologists and other physicians. Thus the College can exert strong professional leadership but not compulsion over its members and their colleagues.

The committee is aware of the growth of federal interests, programs and agencies in the medical and radiological areas in the past two decades. There now exist recognized areas of overlap concerning the responsibilities for physician education and discipline which historically have been accomplished by the medical profession but currently are being duplicated by federal activities.

During the growth of these programs, medical organizations including the College have called upon the Congress and upon the Public Health Service, the Atomic Energy Commission and other federal agencies for various types of support. In other instances, federal agencies have called upon professional societies for support, advice and manpower. We believe that such cooperation is desirable and productive. Examples will be cited below.

The key to College activities is education of physicians, of technologists, physicists and other scientists, of health providers and of the public. Extrapolations from the 1970 X-ray Exposure Survey by the FDA's Bureau of Radiological Health would suggest that the nation's 15,000 specialists in radiology are responsible for about two-thirds of the diagnostic medical x-ray examinations received by Americans each year. Those radiologists performing radiation therapy account for virtually all such services to Americans. Radiologists also perform a majority of diagnostic examinations utilizing radioisotopes, ultrasound pulsed beams and thermographic emissions.

Over the years, the College has exerted leadership in the setting of safety and practice standards for radiation uses in medicine. It is an organizational sponsor of the American Board of Radiology, which began examining candidates for certification in 1934. Its members contributed to the Manhattan project which developed the atomic bomb. The College is a sponsor of the National Council for Radiation Protection. College members supported the creation of what is now the Bureau of Radiological Health in 1957.

The College supported passage of the Atomic Energy Act of 1959, which established the agreement state concept and served as a foundation for most state radiation control programs. We enclose for record testimony presented to this committee for the College nine years ago in support of what became the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602).

(Enclosure 1) Enclosure 1 is available in committee files.

Twelve years ago, the College retained a legislative consultant to provide information to the Congress. Eight years ago, it expanded its Washington presence to provide similar liaison to executive branch agencies. The College provides numerous statements and bits of testimony to congressional committees and frequent responses and suggestions to federal agencies such as BRH, the Environmental Protection Agency, the Nuclear Regulatory Commission, the Occupational Safety and Health Administration, the National Institutes of Health, the National Institute for Occupational Safety and Health, the National Science Foundation and others as appropriate. This is a responsible record.

One principal issue underlies the uses of medical radiation for diagnosis or treatment of patients. The radiation exposure, plus the cost, effort and time, must be justified by benefits to the patient. This concept is discussed in the introduction to "X-ray Examinations: A Guide to Good Practice," which was published jointly by ACR and BRH and distributed to more than a half million health practitioners in 1970. A copy is attached for the record.

(Enclosure 2) Available from U.S. Government Printing Office—stock number 5505-0003.

A medical x-ray exposure is deliberate. It is the product of a clinical need and decision by a physician entrusted with the care of a patient. The exposures are made using precise techniques and protocols which limit exposure to the body part or organ in question and which employ only the necessary number of views to demonstrate or rule out the suspect disease or condition.

In some instances, the x-ray finding is conclusive. The hurt ankle is either fractured or sprained. The mass in the brain is definitely metastatic, or it is not. In others, the x-ray finding is correlated with other clinical and laboratory findings for a diagnosis. In each instance, a diagnostic benefit is anticipated from the decision to accept a small radiation exposure.

In the area of radiation therapy, it has been estimated that some two-thirds of all cancer patients are treated by high energy radiation. Most commonly, this is now combined with surgery or chemicals and the results are often enhanced. Therapeutic levels of radiation are several thousand times as high as diagnostic levels and are intended to destroy tumor cells while having a lesser effect upon normal cells adjacent to the tumor. The ranges of energy used (5000 to 7000 rads) would be many times lethal if exposed to a person's whole body. They are tolerated if delivered in increments to the tumor-containing area.

It is possible to impose standards and specifications for x-ray equipment performance as done in Public Law 90–602 and as implemented by state radiation control programs. It is possible to establish voluntary or public credentialing mechanisms for the physicians and helpers who perform x-ray examinations and treatments. But the decision to perform an x-ray examination, the selection of techniques and the assessment of benefits represent medical judgments, made individually by physicians for individual patients. They are not, in our opinion, a proper area for legislative or regulatory activity.

Since 1929, the NCRP and its predecessor committees have provided advice to the radiation community and to federal agencies on safe approaches and practices. Since 1964, it has functioned under a federal charter.

Its constant monitoring of the scientific community and its considered reports embody the basic knowledge of radiation phenomena available to that community. Its reports and those of the several international commissions are the repositories of the combined wisdom of radiation scientists.

Thus, it may be said that the radiation community understands the effects of high and low levels of radiation better than do other scientists understand many effects of toxic substances and chemicals widely used in today's environment. The action of radiation on living tissue is more clearly demonstrable than the effect of aspirin, for example. Yet, there is much still unknown. The reliance of the linear non-threshold hypothesis for worst case extrapolation of effects from observable high dose levels to non-observable low dose levels—such as those involved in diagnostic radiology—is an uncomfortable basis for public policy. The public confusion over radiation effects from nuclear detonatons and x-ray examinations and the confusion even in some scientific circles between personal risks and populations risks all contribute to a current furor about radiation uses in medicine, in power generation, in transportation and elsewhere.

Thus, the first and primary problem in the radiation world upon which the federal government can bring a positive effect is in the increased support for basic and applied research on radiation phenomena. A decade ago, the Atomic Energy Commission was a major supporter of such research. The Atomic Bomb Casualty Commission and its successor contributed much of the information known about high dose effects upon a population. Much program support centered in the AEC has been lost with the restructuring of that agency and the broadened mission of the Energy Research and Development Administration. Radiation programs within the National Institutes of Health are scattered. The National Cancer institute supports projects relating to radiation therapy.

The National Institute of General Medical Sciences supports a much smaller group of projects relating to diagnostic radiology. The Bureau of Radiological Health supports a small group of basic research efforts. But a strong commitment and bureaucratic focus for radiation science is lacking in the federal establishment. There are no "line items" for radiation research. Such a focus has been sought by the radiologic community and is felt to be badly needed.

Similarly, support by federal agencies for the review activities of the NCRP has lagged in recent years and should be expanded to allow vigorous efforts by the NCRP's expert committees.

A second vital problem is the support for the training of physicians, scientists and technologists to work in medical radiation. With the current national emphasis upon the recruitment and training of primary care physicians, many academic radiologists fear a loss of support for their activities. Primary care physicians have an understanding of radiology but they are not adequately trained to perform and interpret x-ray examinations and to administer radiation therapy. Thus radiologists anticipate a continuing and expandng demand upon their specialty. The understanding and support of the Congress for programs in academic radiology at current levels will be essential. A current study by the American College of Radiology suggests that the specialty may be slipping behind numbers of new radiologists required to respond to national needs.

A third problem of great consequences arises in current proposals to limit national capital expenditures for health facilities. Dramatic breakthroughs in instrumentation such as CT scanners and linear accelerators for cancer treatment are expensive. Their acceptance by clinicians and their proliferation into American communities seeking better health care inevitably precedes the kind of demonstrable proof of efficacy which is desirable in justifying large expenditures.

The advent of the planning agencies established under section 1122 of the 1972 Social Security amendments and under various provisions of PL 93–641 have had an immediate effect of accelerating community competition for expensive facilities like CT scanners. Stringent national ceilings upon capital spending for health could have the unintended effect of freezing the state of the art in radiology.

More specific issues will be discussed in response to subsequent questions. The Congress was responsive in 1975 to questions about the safety of passengers and transport workers who become involved in the shipment of radionuclides for medical uses. No further legislation is needed here, in our opinion. Most of the state radiation control agencies have expanded their capabilities to cooperate with Department of Transportation agencies having primary federal responsibilities. Federal regulations are adequate, though federal enforcement is limited by the size of agency staffs and resources.

Similarly, the state radiation programs have matured to the extent that they have assumed primary responsibility for facility inspection and accreditation programs in their jurisdictions. Some 25 states are "agreement states." Others have comparable capabilities without specific authority over nuclear byproducts.

In the area of radiation disaster response, radiologists and radiologic technologists are aware that their professional knowledge is the only community resource in this area in most American communities. In 1962, the ACR prepared a prize-winning project to provide radiologists with specific response capabilities for nuclear disasters. Much of this material is still current and is incorporated in community plans where those still exist.

Disaster preparedness efforts have had low national priorities since the termination of atmospheric nuclear tests. On several occasions, the College has urged expansion of such efforts.

The current problems created by competitive federal agency programs and regulatory efforts will be discussed in detail in response to another question. They are seen as a significant dilemma requiring resolution by someone.

Question 2. Please provide the committee with a brief introduction to the responsibilities of the College, its role in radiation health safety, education and training programs, etc.

Answer. This addressed in general in the response to question 1 (see above). The College publishes a catalog of materials available for the education of physicians and technologists. These include weekend seminars, self-evaluation materials, movies, slide sets, lectures, fellowship programs and a sophisticated learning laboratory developed in cooperation with the Bureau of Radiological Health. Copies of the current catalog are attached to this report. (Enclosure 3). Available from American College of Radiology, 20 North Wacker Drive, Chicago, Illinois 60606. In addition, other radiological societies sponsor the major journals and conventions of the specialty.

Retention of membership in the College, beginning this year, is dependent upon each radiologist member attaining at least 150 hours of verifiable continuing medical education under the pattern developed by the American Medical Association.

Among the materials developed are a myriad of devices and training aids for use in radiation protection programs. These include films, slide sets, booklets, action programs and cooperative efforts with BRH and other public agencies. Cited above was the publication, "X-ray Examinations: A Guide to Good Practice," which provided general information to more than a half million health practitioners when it was released in 1971 by ACR and BRH. Two years ago, a film bearing the same title was produced by the College with support from E. R. Squibb and Sons. Several hundred prints are in circulation and have been seen by thousands of physicians and technologists. A teaching package for technologists based upon the film is currently under development.

Three years ago, the College distributed to all of its members sample gonad shields for use in abdominal examinations of males. This program was developed with BRH and the distribution effort was funded from College dues.

On June 20, the College will co-sponsor one day of the program at the Conference of State Radiation Program Directors to discuss current problems with mammography, CT scanners and other common dilemmas.

A list of other College activities and programs such as those few detailed above would be long indeed. Those cited are indicative of a responsibility perceived and accepted.

Question 3. Please comment on the proposals for licensing and certification of radiologic technicians.

At the time of this response, there is no current measure before the Senate. Mr. Koch has offered several versions of a federal standards proposal in the House. There have been previous bills offered in the Senate by Mr. Randolph. The College has testified on many of these in opposition to their enactment.

The basis of the College opposition is that the substance of these bills creates a public mechanism which duplicates but fails to improve on existing voluntary programs for credentialing of radiologic technologists and accreditation of schools. We enclose the most recent ACR testimony in December, 1975, to the House Committee on Commerce. (Enclosure 4 is available in Committee files.) We also enclose a report of a study of the three active state licensure programs conducted jointly by the ACR and the American Society of Radiologic Technologists. (Enclosure 5 is available in Committee files.)

Question 4. Please provide the committee with the College's position with regard to the adequacy of current procedures for licensing and handling certification of individuals working with the NRC or state-controlled isotopes used in medical research or for diagnosis and treatment.

Answer. We enclose a copy of a letter from the College responding to a recent NRC inquiry of a similar nature. (Enclosure 6 is available in Committee files.) In substance, we think that existing training and certification programs are adequate and that no additional efforts by NRC, in conflict with programs of the Food and Drug Administration and the states, would be warranted.

Question 5. Please provide the committee with any comments on problems perceived which are related to the current dispersion of radiation health and safety responsibilities within the federal agencies.

Answer. The College has been concerned for more than a decade about the redundancy of federal efforts in some areas and the absence of effort in others. In 1970, the ACR formally petitioned the secretary of Health, Education and Welfare to make an analysis of HEW programs and responsibilities involving ionizing radiation. The matter was referred to the assistant secretary for health and no action was taken. For example, within HEW, several of the National Institutes of Health fund some extramural research efforts. Within the Food and Drug Administration, the Bureaus of Drugs, Radiological Health, and Medical Devices and Diagonstic Products all seem to have areas of responsibility for radioactive materials, x-ray products and guidelines. In addition, the Environmental Protection Agency has asserted a mandate to issue guidelines on medical uses of radiation for federal health facilities. Recently, the Nuclear Regulatory Commission has asserted an interest in expanding its role in regulation of medical uses of radiation. We have seen a draft of proposed occupational regulations for radiation workers from the Department of Labor's Occupational Safety and Health Administration.

The amount of costs to the taxpayers from this bureaucratic duplication cannot be estimated but it must be considerable. The amount of cost to health providers in attempting to follow and comply with overlapping and sometimes conflicting federal ukases is also considerable. This is particularly true when the state programs are counted into the pattern.

Recently, radiologists have been particularly concerned about implementation of the FDA's new medical device authority in the field of radiology. Despite the existence of functioning programs within the Bureau of Radiological Health, where a scientific competence is found and where a viable compliance program already exists, the Bureau of Medical Devices set up its own panel and its own mechanism for classifying x-ray products. With the substantial responsibility

BMDDP has in areas where no existing mechanism was in place, this is a detraction from other obligations, a duplication of effort and a duplication of burden upon radiologists and their suppliers.

Members of the BMDDP radiology panel have encountered substantial difficulty in providing their expertise to the FDA because of the insistence of officials upon the use of protocols, classifications and inclusions of types of products which are not appropriate for diagnostic or therapeutic radiology. Radiology devices are never given to patients for their own use, with or without supervision. The devices and products are used by qualified personnal according to standard protocols. In addition, the electronic and mechanical portions of x-ray equipment often use components which are common to products not used in medicine. A literal application of the full requirements of the law will result in (1) a significant escalation of costs for these components where the manufacturer complies with FDA paperwork, or (2) withdrawal of the manufacturer and the component from medical equipment availability, or (3) a refusal of manufacturers to make requested changes in equipment to enhance performance.

Obviously, the BMDDP is mandated by specific legislative and regulatory instructions and should and must place safety first. However, a modicum of restraint would be most welcome.

The EPA bases its concern for medical radiation on the mandate which it assumed from the Federal Radiation Council. The series of FRC reports had avoided specifying medical radiation practices as being inappropriate for federal guidance. The EPA position, in our opinion, is contrary to specific instructions in President Nixon's Reorganization Order No. 3 in 1970 which established EPA and left medical radiation responsibilities with the Public Health Service. The jurisdiction has not been resolved, but needs to be.

Similarly, the NRC has historic claims to work with medical users of radionuclides. However, in 1970, the AEC and the FDA ended an agreement under which FDA had refrained from establishing its usual domain over radioactive materials. Since then, FDA through its Bureau of Drugs and Bureau of Radiological Health, has built a suitable regulatory program for these products. And, as we indicated above, the profession has created satisfactory mechanisms for training and certifying personnel to work with radioactive materials.

The activities of other federal agencies are tangential to direct radiation safety and control responsibilities. None of them are creating any substantial problems at this time. Again, the major dilemma is the diversity of primary interests and often a lack of expertise in a complex field which leads to delays and redundancy when problems do arise.

Question 6. What are the College's efforts with respect to ensuring the safety in the use of new devices such as utra-sonic devices, lasers, etc?

Answer. The College's concerns and activities are focused upon those areas involving medical imaging and the use of high energy radiation to treat disease. The College has not been involved with surgical lasers, microwaves, crytherapy units, therapeutic ultrasound, phototherapy or other such energy sources for medicine.

It has been involved with diagnostic ultrasound, with thermographic emissions and with holography. This involvement comes through the function of expert committees which write guidelines and other advice, produce seminars, training manuals, serve as College interfaces with federal agencies and voluntary standards groups, and generally try to estabish a reasonable and rational context for medical applications of new modalities. Frequently, College efforts are coordinated with those of the Bureau of Radiological Health in these new areas.

Question 7. Has the College limited its concerns primarily to ionizing radiation devices? If so, does the College see itself as playing a similar role in the medical field with regard to increasingly large numbers of medical devices employing nonionizing radiation?

This question is largely answered by our response to the previous question. The x-ray beam is still the primary and numerically dominant form of energy used in medical diagnosis. In new and sophistical forms like the computed tomographic scanner, it has much promise for the future. The elements, dimension and nature of risk from exposures to ionizing radiation are reasonably understood, though much work remains to be done. The addition, in the past 30 years, of the multiplicity of imaging methods based upon internal radionuclides depends upon the same basic physical and biological disciplines and protocols.

The College has now established a separate commission on ultrasound. It has encouraged the support of activities to explore and define the possibility of biological effects. As such, the College can offer an opportunity for synthesis of such efforts. Such a process is underway in the field of diagnostic ultrasound.

As other new energy forms and modalities are offered for medical imaging or the treatment of cancers, radiologists will expect the College to provide mechanisms for their guidance.

Question 8. What effort is the College exerting to ensure that radiologists and technologists are thoroughly familiar with recommended minimum dosages and prescribed procedures?

Answer. The language of the question reflects a misunderstanding of the fundamental concept of good radiation practice. With one or two exceptions, there are no "minimum recommended dosages" for medical radiation exposures. Instead, the conscientious user of medical radiation achieves his objective (i.e., a medical diagnosis or biologic response to a tumor) using as low as practicable a radiation exposure. Neither the College nor the NCRP nor other responsible national and international bodies have made recommendations for doses in specified procedures or for cumulative doses to individual patients from any and all needed radiologic procedures. One state, Illinois, has recommended maximum doses for certain examinations.

Instead, to foreshadow the next question, the College has worked with industry, with government groups and with voluntary agencies to improve the state of the art in radiology. For example, the College was active in efforts to induce the Xerox Corporation to manufacture and market units which would allow radiologists to obtain mammographic examinations of women with possible breast cancer with both a better image and a lower radiation exposure. The College also worked with x-ray film manufacturers to devise a conventional film which would produce clear mammographic images with low radiation exposure.

Radiologists, technically, must work within the state of the art. However, they make considerable efforts to improve the state of the art so that satisfactory examinations can be obtained with a minimum of exposure.

The second half of the question referring to prescribed procedures deserves a strongly affirmative answer. The College has been active in seeking protocols to optimize diagnostic results from minimal radiation exposures. It has had projects in mammography, in chest and colon radiology, in occupational programs such as pre-employment low back x-ray requirements, and in many others. This all relates to the premise that any radiation which does not contribute to a diagnostic result is wasted. Too much radiation for the technical factors concerned makes a poor image. Too little radiation makes a poor image. Poor images are wasteful. As an example, we enclose a copy of proceedings of a conference on the use of low back x-ray studies as part of pre-employment physicals which the College conducted under contract with the National Institute for Occupational Safety and Health.

(Enclosure 7 is available in committee files.)

Question 9. How does the College interact with industry in recommending specifications for equipment design and manufacture to ensure that coninual improvements are made to reduce the medical exposures from such devices.

Answer. Radiology was the first medical discipline to be entirely dependent upon technology for its product. Many radiologists are aware of physics and engineering principles. Radiology installations are supplied by manufacturers on what amounts to a custom order basis. The interplay between radiologists and manufacturers has historically been close and fruitful to both.

In recent years, the numerous activities of the College relating to equipment have been centralized within a Commission on Equipment and Facilities. This commission has ongoing activities relating to the several categories of equipment. It is the site of the College's efforts toward quality assurance in diagnostic radiology. It provides a forum in its seminars and publications for an exchange between knowledgeable radiologists and industry executives and engineers. Industry representatives routinely meet with ACR committees to provide and receive input. An example is the development of a low-dose mammography film using a single intensifying screen which was developed by a major company after its chief of research had attended a College forum on the problem. This allowed a major move forward in the state of the art of mammography.

With the advent of FDA responsibilities under PL 90–602, it is now routine for ACR committees to invite representatives from the Bureau of Radiological Health to meet with and contribute to its committees on equipment, radiation safety and new developments.

One other point is worth remembering. Patients receive only occasional and partial exposures from medical radiation. The radiologists and technologists who work in the area have an on-going occupational hazard which they are immediately interested in minimizing. This interest is shared with industry, with government and with anyone else who will listen.

Question 10. What reactions does the College have to claims that the increased use of diagnostic x-rays is the result of attempts to protect physicians from malpractice suits and thus, may be offsetting the improvements in techniques designed to reduce exposure?

Answer. There is inescapable and regrettable truth to assertions that some unmeasurable number of diagnostic x-ray examinations are made for purposes other than the immediate medical needs of the patient. To ACR leaders, this is a major problem which goes beyond either radiation limitations or cost controls to reach into the profile of good medical care. The College has been explicitly concerned and involved with this problem since the beginning of its efficacy project in 1970. "Efficacy" here is described as the impact of the x-ray examination results upon the management of the patient, presuming that the information which potentially could have been gained from the x-ray examination was gained.

The ultimate task is to define those patterns of clinical practice which lead a clinician to decide to include a diagnostic x-ray examination as part of his patient workup. The examination has to be capable of contributing information which will confirm or refute the clinical suspicion. Either confirmation or refutation may be equally efficacious if the positivity achieved by the x-ray examination is a reasonable increase over the positivity of other clinical findings.

The ACR efficacy study has been designed and implemented as a prospective effort to work with clinicians in rating their uses of x-rays. The vital questions devolve upon which x-rays under what circumstances are efficacious. The design of the study is complex. The decisions are complex. The answers have been slow in arriving.

The College has been fortunate in having support from the Public Health Service for the design and testing stages of the efficacy study. Recent funding has been curtailed severely at a time when the survey protocols were ready for broadened application. Since the kind of data to be derived from the efficacy study is fundamental to rational decisions about changing patterns of x-ray referrals, about measuring yields of clinical information and about saving both radiation exposure and health costs, a renewal of federal subsidies would make possible the next stages of the effort in a timely manner.

To return to the context of the question, physicians are trained to err, if inescapable, on the side of doing too much, rather than too little, for patients. Most commonly, the question of malpractice for a clinician hinges upon the adequacy of his care, not upon the quality of the x-ray examination. If the diagnosis was missed for want of an x-ray study, and if it is alleged that x-ray examinations are routine in patients with certain symptoms, then it is easy to suggest negligence if the x-ray examination was not requested. The data from an efficacy study will at least attempt to quantify for clinicians the probability of obtaining additional information from x-ray studies. A paper from Loop and Bell, from the New England Journal of Medicine, has addressed this concept, and it is attached.

(Enclosure 8: Reprinted from New England Journal of Medicine 284: 236–239, February 4, 1971).

AMERICAN COLLEGE OF RADIOLOGY,
Chevy Chase, Md.,
June 3, 1977.

Mr. RICHARD CUNNINGHAM,
Acting Director, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C.

DEAR MR. CUNNINGHAM: The comments below are offered on behalf of the members of the American College of Radiology with regard to the questions raised by the NRC in its inquiry about NRC regulation of medical uses of radioisotopes in the April 21 Federal Register and in the open meeting on May 6. The specific responses were prepared by the Commission on Nuclear Medicine of the College.

As we did in our earlier letter, we would emphasize our increasing concern about the cost of implementing new federal regulatory programs. As you are aware, a major thrust of the Carter Administration is to contain the soaring costs of health care. One such soaring cost is the expense, time, personnel and difficulty involved in complying with regulations. We suggested earlier that it is our considered opinion that the current combination of public and voluntary standards and regulations are adequate to maintain safe and effective uses of radioisotopes in medicine.

It is now our understanding, as detailed below, that the several areas historically tended by the Atomic Energy Commission are now firmly occupied by active programs of the Food and Drug Administration. To duplicate these now by expanding NRC activities or initiating new ones is not justified.

Responses to your 10 questions follow:

(1) *Evaluation of the physician's clinical qualifications.*

While we acknowledge that the AEC and more recently the NRC has fulfilled this role in the past, we feel that our training programs and the certifying process provided by the American Board of Radiology, the American Board of Pathology and the American Board of Nuclear Medicine is a superior method to measure clinical competence. Furthermore, if you plan to adhere to your recent requirements of 500 hours of clinical experience and 200 hours of basic science training it is unlikely that you will receive applicants from individuals who have not come from a well structured program.

(2) *Selection of patients for diagnostic or therapeutic procedures.*

This is clearly the practice of medicine and therefore is the responsibility of the licensed physician. Review mechanisms such as the PSRO and hospital utilization review committees mandated by Congress are designed to address this issue. Further, it is our conviction that neither the NRC nor any other agency, bureau or governmental body develop regulations to meaningfully control judgment decisions.

(3) *Selection of instruments to be used in performing diagnostic or therapeutic procedures.*

Again, as in (2), this is a judgment decision which only can be made by a qualified licensed physician and should not be the concern of the NRC.

With regard to the performance standards, Congress has given the FDA responsibility to regulate medical devices. NRC involvement would only lead to more confusion. It is unfortunate that our agencies and bureaus have lost faith in the market place which has been extremely effective in eliminating substandard equipment in the past.

(4) *Selection of radioactive drugs or devices to be used.*

Again, as in (2) and (3), this is the practice of medicine and is not an area in which the NRC should be concerned. The FDA controls the manufacture of drugs and approves the use of drugs for specific purposes as being safe and effective. While it is true that a licensed physician can use these drugs for other than the specified purposes, this should cause no concern to the NRC. A diagnostic radionuclide proven safe and effective for one purpose will always be safe for another, regardless of whether it is or is not effective for that unapproved use. This is an essential physician's prerogative. Not infrequently we have observed unexpected effectiveness of diagnostic agents which if we were prohibited by law to explore would significantly impede progress.

(5) *Selection of procedures to be performed.*

Again this is the practice of medicine and should not be the concern of the NRC.

A physician's specialized training, state licensure and relicensure requirements, the certification and recertification process and the yearly reviews of hospital staff privileges by peers guarantees far better than could any regulation the physician's ability to make decisions.

(6) *Selection at dose level (quantity of radioactive material or radiation dose) to be used.*

We feel that the NRC no longer needs to be concerned with the selection of dose levels. This area of concern has been assumed by the FDA who advise physicians of recommended dose levels through the package insert. Physicians, as in the choice of drugs, have the prerogative to vary these levels either up or down when in their considered judgment it would be in the patient's best interest.

(7) *Proper measurement of the dose the patient receives.*

In our opinion, methods to insure proper measurement of dose should be the responsibility of the Bureau of Radiological Health and of the medical and scientific community and need not be the concern of the NRC.

(8) *Calibration of diagnostic equipment and dose measuring instruments.*

As in (7), in our opinion, methods of calibration of diagnostic equipment and dose measuring instruments is the responsibility of the Bureau of Radiological

Health and the medical and scientific community and need not be the concern of the NRC.

(9) *Qualifications of paramedical personnel, such as technologists, nurses, radiopharmacists and radiological physicists.*

In our opinion this is not an appropriate area of concern for the NRC.

Mechanisms already exist to measure the qualifications of these individuals. Physicists are certified by the American Board of Radiology upon the satisfactory completion of both a written and oral examination. Pharmacists are licensed by state pharmacy boards and are presently organizing a certification board for radiopharmacists. Technologists are presently certified in nuclear medicine technology (NMT) by the American Registry of Radiological Technicians (ARRT) and the American Society of Clinical Pathologists (ASCP). A third registry is being formed by the technologist section of the Society of Nuclear Medicine. Presently the ARRT examines the vast majority of candidates for NMT certification and since July 1976 will accept only canddiates who have completed an AMA approved program in nuclear medicine technology.

Despite our efforts to increase the number of approved programs the present output of these qualified technologists falls considerably short of the demand.

We have no firm data on the number of non-certified nuclear medicine technologists presently in the labor pool. We suspect it is large. Most of these individuals are without formal training and while we readily acknowledge that such on-the-job training varies considerably in quality and that it would be desirable that all nuclear medicine technologists be products of our AMA approved programs this simply is not the real world. Any federal regulations which would further reduce the already short supply of technologists would be seriously inflationary and would solve nothing.

(10) *Reporting to the NRC, the patient, and/or the patient's physician, misadministration of radioactive material or radiation from devices incorporating radioactive material.*

The question of importance here is the definition of the term, "misadministration". If this implies a dose administration which could seriously affect the health and safety of the patient and represent a significant breakdown in radiation safety technique, we feel you should be informed so that your subsequent investigation could correct the reasons for this breakdown and perhaps be useful to other institutions. If you are referring to unimportant misadministration such as giving 99mTC pyrophosphate instead of 99mTC sulfur colloid, a human error which will occur a certain percentage of the time, then we are strongly opposed since reporting such misadministration could benefit no one and there is probably no way that we could change our staff procedures to correct this.

Thank you for the opportunity to comment upon this subject.

Sincerely,

OTHA W. LINTON,
Director, Government Relations.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND THE AMERICAN COLLEGE OF RADIOLOGY ANSWERS

Question 1. During the course of your oral testimony you identified the "absence of a focus for radiation-related research within the federal government" as a current concern of your organization. Please amplify this comment, and if possible, make suggestions as to which agency or agencies would serve as an appropriate focus.

Answer. During a recent discussion with officials at the National Institutes of Health, one member of the director's staff challenged the assertion by the College that radiology research is under-supported. "Don't radiologists participate in research projects in every area of clinical medicine?" he asked. "Aren't they relied upon by their colleagues in many research projects?"

The nature of the questions epitomized the problem as seen by radiologists. They seek a coherent federal interest in research about radiology—about clinical problems requiring radiological solutions, about improved procedures, techniques, equipment for both diagnosis and therapy, about basic radiation physics, radiobiology and epidemiology and radiation effects, about the yield or efficacy of radiation procedures and, of course, about radiation safety.

As we suggested earlier, no federal agency is charged with an overall view and responsibility for these areas and problems. We did not mean to suggest that all federal funding should be monolithic. Rather, we suggested that with such funding as exists in various federal agencies, there is no coordination, no policy determination, no avoidance of duplication or coverage of vital but undersupported areas of activity.

Since the earlier hearings of the Senate committee, the director of the National Institutes of Health has responded to requests from the academic radiologic community for a study of NIH activities in support of radiation science. The data gathering process is just beginning with the full help and support of the radiology groups. The MEDLARS search and other studies likely will parallel an effort made three years ago by the ACR which indicated that research in radiation therapy and underlying radiation biology are reasonably well organized and funded, principally within the National Cancer Institute. Earlier programs supporting the training of radiotherapists, dosimetrists, therapy technologists and others have been terminated, leaving an estimated gap of several hundred persons between national supply and demand in those disciplines.

It might be pointed out that the NIH mission is not the production of medical manpower. Currently, it is difficult to discover just whose mission that is, the intent of Congress notwithstanding. With the current reasonable emphasis upon primary medical care, it must be asked whether many American communities can receive optimal radiation therapy in centers requiring a full range of high energy radiation therapy devices and a team of dedicated physicians and other scientists, when these people remain in short supply with no organized programs devoted to their recruitment and training within the federal funding mechanisms.

One objective of radiobiological research is to determine the impact of ionizing and other radiations as a carcinogenic agent and as a therapeutic agent for cancers from any cause. We stated in our earlier comments that a substantial and growing body of information is extant about radiation effects. Yet, for example, current information is not adequate to allow for precise planning of radiation therapy for many tumors. Current information is not adequate to support or disprove the linear non-threshold hypothesis (about which more in the next question and answer) or to undergird scientific and policy decisions about population radiation exposures for various reasons.

One current controversy in this regard is the discussion of uses of mammography as a case-finding procedure for women in certain age groups who have not yet displayed clinical symptoms for breast cancer. Clinical studies have suggested strongly that occult cancers of the breasts can be found by mammography earlier than they are normally by physical examination. As yet undetermined is the question of whether breast cancers found earlier result in better salvage and reduced mortality. Also under challenge is the exposure of possibly millions of non-symptomatic women to X-days of their breasts as a possible source of cancer induction. There is no directly observable evidence that X-ray exposures of the breast at dose levels used for mammography have caused cancers. However, using the linear non-threshold hypothesis and extrapolating from studies of exposures at higher levels, it is possible to project statistical possibilities of such cancer induction.

Perhaps the critical point about the mammography issue is that the National Cancer Institute has only a limited responsibility for the 27 demonstration centers which it has helped to fund. Nowhere else in the federal government is there a direct responsibility. The Food and Drug Administration is considering issuing guidelines, but principally for the purpose of addressing radiation protection, not medically efficacy. The Environmental Protection Agency has issued guidelines to federal facilities but to no one else. To the extent that breast cancer screening is a public policy and public responsibility, it is not addressed in an organized fashion by federal agencies.

These examples may serve to make the point. There are additional radiation related programs elsewhere in government in the Department of Defense, the Energy Research and Development Administration, the Nuclear Regulatory Commission, and the Department of Commerce's National Bureau of Standards. But there are no mechanisms by which the government coordinates these efforts.

Most of the problems and efforts described above relate to health. Either they relate to the health of persons receiving radiation for medical purposes or they relate to health effects from occupational or environmental radiation exposures. It has been the posture of the American College of Radiology that uses and controls of ionizing radiation are essentially health issues. In testimony to various congressional committees over the years, we have consistently favored placing these responsibilities within the Department of Health, Education and Welfare, with a strong mandate for liaison with the other agencies of government where responsibilities for energy, the environment and other uses overlap.

It was the observation of our expert committees that the Federal Radiation Council, lacking any natual constituency and being devoted only to regulation was not an adequate approach. There needs to be a direct responsibility and a direct relationship to the various involved publics which can be achieved only by a line agency.

Within HEW, we have pointed out a diffuseness of responsibility for radiation programs which results in some things being done twice and others ignored. It may be appropriate for NIH to continue being responsible for basic and clinical research, for FDA to be responsible for radiopharmaceuticals, radiation equipment and safety, and for someone to be responsible for manpower. But there needs to be a management level coordination, probably in the office of the assistant secretary for health. At least, this would be our basic suggestion.

Question 2. During your oral testimony you stated "radiation scientists have postulated a worst-case theory called the linear non-threshold hypothesis." Please amplify why you consider the linear hypothesis the "worst-case" situation. Doesn't the possibility exist, in theory at least, for less than a linear or more than a linear response at low radiation doses?

Answer. First of all, let us distinguish between "linear" and "linear non-threshold" responses. The curves of Figure 1 will assist in this discussion. These curves are schematic only and indicate absorbed dose-effect relationships for moderate values of absorbed dose that you postulated in your query. Lines B and D both indicate linear relationships between effect and absorbed dose, that is, they are both straight lines. However, line D indicates that no effect is observed below the intercept of this line with the absorbed dose axis. This type of curve is sometimes called a linear-threshold dose-effect relationship. The line B, because it passes through the zero value of the effect at zero absorbed dose (above the natural incidence and natural background of radiation), is called a linear no-threshold dose effect relationship. Sometimes this is referred to as indicating proportionality between absorbed dose and effect.

We believe that what you have called "less than linear" or "more than linear" response can be exemplified by curves C and A, respectively. For curve A the slope has an initial relatively large value near the origin which decreases as the absorbed dose is increased. For curve C the initial slope is small and it increases with absorbed dose.

Figure 2 also presents absorbed dose-effect relationships. Curve E of Figure 2 exemplifies the type of dose-effect relationship that is generally observed for electron or X– or gamma-ray (i.e., low LET) irradiation. The curve starts out from the origin with a small slope which increases with absorbed dose for moderate values of absorbed dose and then decreases to a plateau and, in some cases (as in this figure), falls off beyond the plateau. The plateau is interpreted as resulting from the "killing" or sterilization of cells that would otherwise have produced an effect. Let us assume that we have experimentally determined the magnitude of the effect for a given absorbed dose at some point such as a. If we project a linear no-threshold dose-effect relationship from this point to the origin, this may be represented by the dotted straight line F. It is seen that the slope of line F is larger than the slope of line G which represents the slope of curve E near the origin. It is thus seen that for dose-effect relationships exemplified by curve C of figure 1, the effect predicted under the assumption of proportionality is larger than the true value for the low doses of interest in radiation protection.

Of course, one must exercise some caution in such interpretation. It is seen, for example, that if the data point from which a linear no-threshold relationship is projected were b in Figure 2, such a conclusion would not be valid.

There are few data on radiation effects on humans even at moderate values of absorbed dose such as point a (Fig. 2), so one must depend upon information obtained from irradiation of cells and animals to form an opinion on the dose-effect relationship for man at low values of absorbed dose (far below point a). This approach was used by Dr. A. C. Upton, the present director of the National Cancer Institute, in his paper entitled, "Radiobiological Effects of Low Doses, Implications for Radiological Protection," published in Radiation Research, 71, page 51, 1977. (A copy of his summary is enclosed.)

It was on the basis of such reasoning that the American College of Radiology made the statement that the linear no-threshold hypothesis represents a "worst case theory."

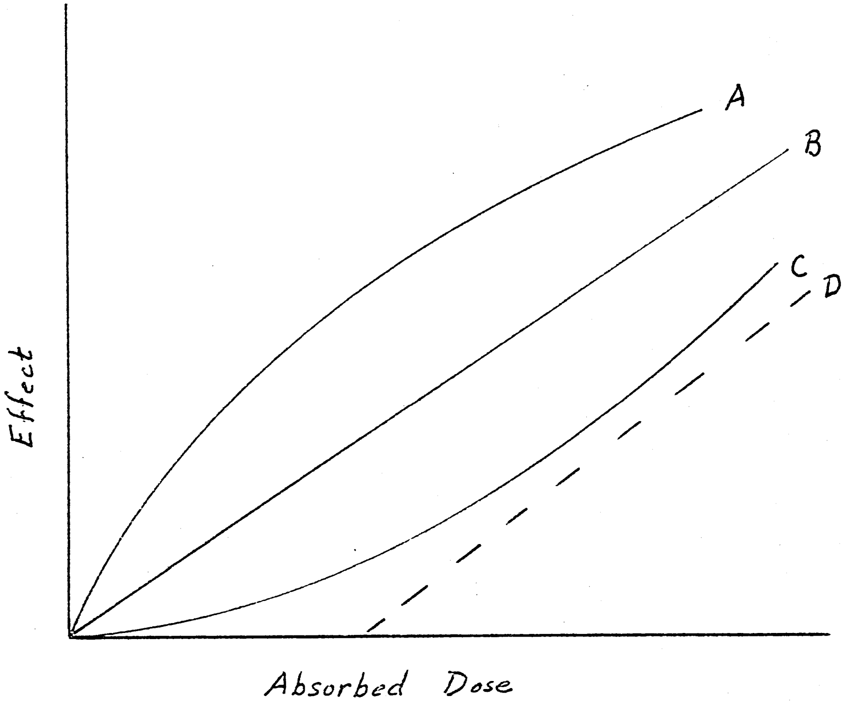


FIGURE 1

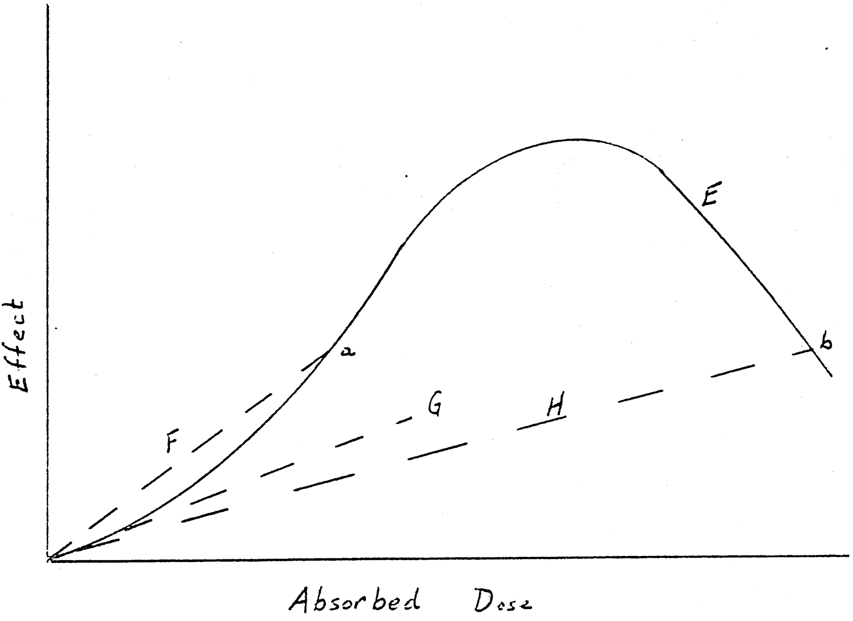


FIGURE 2

Question 3. During the course of the hearing, Mr. Linton stated, with respect to the efficacy study, that the American College of Radiology is about ready to issue some of the preliminary reports. It would be useful to the committee to acquire whatever preliminary information is available at this time.

Answer. Attached is the report of the first phase of the efficacy study, just completed. The summary as well as the entire report is submitted. Currently, the project has lost its funding from federal agencies and its future is in doubt. The College has contributed significantly from its own resources to this effort from the beginning. However, it does not now have the resources to continue the project at a productive level. With the current federal interests in efficiency and productivity of health services, it would be ironic to lose the benefits of this extended investigation just as it was becoming productive. The ACR will continue to seek support elsewhere but the difficulties cited above point out its need for better review and coordination of efforts in radiology at the federal level.

Question 4. Do you support the mandatory licensing of radiologic technicians?

Answer. The American College of Radiology does not favor mandatory licensure of radiologic technologists. Our most recent testimony was presented to the House Commerce Health Subcommittee in December, 1975 and referenced in response to question three in the earlier list. A study of the three active state licensure programs conducted jointly with the American Society of Radiologic Technologists and also referenced in the earlier responses failed to indicate significant benefits to the public health from these three programs.

Question 5. Please document your assertion that federal regulations have made a significant contribution to the high cost of radiology service.

Answer. Our comment was addressed primarily to the impact of the performance standards for diagnostic equipment which were promulgated by FDA in 1974 and to anticipated obligations incurred by manufacturers under the medical device regulations soon to be promulgated by FDA under the 1976 Medical Device Act.

In the instance of the performance standards, a requirement for positive beam limitation has added approximately $1,200 to $6,000 to the cost of each stationary, general purpose diagnostic X-ray unit. Approximately 50 percent of all X-ray systems are of this type. Such systems range in price from $20,000 to more than $100,000. In addition to the initial cost, most of the beam limiting devices have proven to be complex and difficult to operate and maintain, thus adding to the repair costs and down time experienced by the equipment. Other requirements, such as the one for fidelity of beam production within 2 percent of setting, have also added to cost, while delivering a superior piece of equipment. The lifetime guarantee on equipment performance, the level of documentation required of manufacturers and installers and the cost of conforming to FDA's good manufacturing practices requirements all must be factored into the cost of sales and service. No detailed figures are available. And, of course, since 1973, X-ray equipment price rises have been comparable to the general inflationary pattern of other goods and services in this country.

With the implementation of medical device regulations proceeding presently, it is impossible to do more than guess at the added costs involved. We commented earlier on the expressed posture of the FDA's Bureau of Medical Devices and Diagnostic Products that everything used in medicine should be classified and regulated. We are now advised that BMDDP, after two years of establishing radiologic equipment classifications, will shortly turn this area of responsibility over to the Bureau of Radiological Health. This is welcome, if overdue, and might tend to reduce the "double jeopardy" incurred by X-ray manufacturers who already meet performance standards.

Where federal regulatory activities result in better, more reliable equipment than has been marketed previously, we agree that added costs for such equipment are justified. But it cannot be avoided that government regulatory activities do add to costs.

Question 6. Please comment upon Mrs. Rose Kushner's allegation that mammography services are grossly overpriced.

Answer. We heard Mrs. Kushner's comments to the Senate subcommittee. However, we are not provided with any type of documentation or support except for a wistful feeling that something so important to many women should not be too costly.

The College does not recommend fees to its members and does not collect statistics as to the range of fees around the country. However, federal programs and various public and private health insurance carriers do collect such statistics.

The fees of physicians are governed to a very real extent by the levels acceptable to federal programs and to third party carriers using profiles, ranges and review mechanisms. We are not aware from public outcries or complaints of radiologists that these carriers have regarded mammography as being grossly overpriced.

Mammography is among the more demanding of basic X-ray examinations. Most radiologists employ specially trained technologists using equipment limited to examinations of the breast. Where xerographic examinations are favored, the xerox processing equipment adds to conventional film costs. Then, the amount of time spent by most radiologists on the interpretation of the films is much longer than the time required for many other film examinations. All of these factors are properly reflected in the cost of the examination.

Question 7. What is your opinion of the Bureau of Radiological Health's BENT and DENT programs? How might these programs be improved?

Answer. We in medical radiology were aware of but had no part in the DENT program. The ACR was asked to assist in the development of the BENT program and provided much assistance and the cooperation of our chapters in test states. We regard both efforts as worthwhile attempts to measure what is actually happening in two areas of X-ray practice. Both are designed as simple, mail order methods of measuring exposures by use of thermo-luminescent dosimeters which can be used easily and forwarded for centralized analysis. For the uses intended, they are valid survey instruments.

Such programs cannot provide details of why exposures may vary between installations or even from day to day within the same installation. Thus, they are a beginning which should be supplemented by other test methods. BRH and the ACR have jointly been working on extensive quality assurance programs which would involve other instruments to be used by the X-ray facility to monitor the daily performance of X-ray equipment and processing procedures. The effect of such efforts is both to measure performance and to identify and correct problems within a facility. It is axiomatic that improved quality results in lowered radiation doses through the avoidance of retakes and missed diagnoses.

The College has encouraged BRH to devote additional efforts to programs such as BENT, DENT, NEXT (nationwide evaluation of X-ray trends) and other efforts to measure practice, identify problems and enlist the cooperation of the states and of the involved physicians in correcting such problems. It will be necessary for BRH and FDA to exercise regulatory authority in various ways. But we submit that education and cooperation are much more productive ways of improving medical practice.

Question 8. How will the information developed in the efficacy study be disseminated to the members of the American College of Radiology? What level of coverage is likely to be achieved?

Answer. The College has already published selected findings from the efficacy study in its monthly Bulletin which goes to all members of the ACR. Recently, Applied Radiology, an independent publication, carried an article about the scope and accomplishments of the study (a copy is attached).[1] Members of the committee have prepared articles for several scientific publications. More are planned. The College is proceeding with the publication of the report which is attached to this correspondence. Copies will be available to radiologists and others.

In an information sense, the level of coverage of radiologists will be fairly complete. In terms of applications of conclusions, it is too early to say. The committee members are aware that their efforts have stimulated local efficacy projects, medical staff discussions and certain changes in patterns of X-ray practice. For example, from another effort, not directly related to this study, the ACR joined the American College of Chest Physicians and the Public Health Service in recommending that community tuberculosis X-ray screening programs be discontinued.

If the efficacy study is continued and extended into other areas besides emergency room originated procedures, then it would be reasonable to expect that its findings would begin to have significant impacts upon the deliberations of professional standards review organizations and the compensation profiles of various health insurance carriers. It is likely that PSROs and carriers will be quicker to seize upon such data than even the physicians who benefit from efficacy conclusions.

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[1] Retained in committee files.

Question 9. To what extent has there been an attempt at self-policing in the health profession to minimize the risks associated with unnecessary diagnostic X-rays? Is this a feasible and effective course for the health profession to pursue?

Answer. The thrust of our testimony and our responses to the two sets of questions has been toward federal programs which are properly the concern of oversight hearings. We have alluded to prior and ongoing efforts of the College, the National Council for Radiation Protection and Measurements, the International Commission on Radiological Protection, the International Commission on Radiation Unit and Measurement, and various other voluntary bodies. Many of the programs currently underway by BRH were jointly conceived or originated in suggestions or activities of ACR committees.

When the ACR joined with BRH in the 1970 publication of "X-ray Examinations: A Guide to Good Practice," the ACR arranged with the American Medical Association, The American Osteopathic Association, the American Podiatry Association, the American Veterinary Medical Association, the American Society of Radiologic Technologists and others for distribution to their members.

When the ACR undertook a study of the use of lumbar spinal X-rays in pre-employment physical examinations under contract with the National Institute for Occupational Safety and Health, it joined with the American Academy of Orthopedic Surgeons and the American Occupational Health Association in the project. When the ACR undertook training programs to assist physicians with chest X-ray examination requirements for coal miners under the black lung act, it enlisted the support of the American Medical Association, the American College of Chest Physicians, the American Occupational Health Association, the American Osteopathic Association and the American Society of Radiologic Technologists.

All of these were efforts to gather information, synthesize it and disseminate it to interested physician groups.

Earlier, as mentioned before, the ACR had joined with the American Academy of Pediatrics to urge against office fluoroscopy by pediatricians. Recently, the ACR has joined with the American College of Obstetricians and Gynecologists in issuing recommendations for X-ray examinations of pregnant or possibly pregnant women. A few years ago, the ACR worked with BRH to design and test and finally, at ACR expense, to manufacture and distribute male gonad shields of an effective design.

In recent years, with attention being given to the possibilities of damage from radiation exposure and with the growing concern about health care cost increases, considerable attention has been directed within medical circles to the performance of radiological examinations by physicians in other disciplines. Such examinations amount to somewhere in the range of a fourth of all medical X-ray procedures and are performed mostly in physician offices and clinics. They range in complexity from the sophisticated studies of the heart performed by cardiologists to routine looks at fractures and chests by family practitioners. Seldom do these other physician attempt examinations which do not relate to their own area of interest. However, questions have arisen about the competence of these physicians to supervise and interpret X-ray examinations in the absence of any formally documented training. Other questions have arisen about the benefit to the medical system when these physicians make decisions about the need for X-ray studies which result in immediate added income to themselves.

Self-referral radiology has been a concern of radiologists because there is no way that we as a professional society can exert direct influence upon the radiation practices of other physicians. We have outlined above examples of instances where the ACR has worked with other groups to set guidelines for X-ray usage. We do consult with other medical groups when an opportunity presents to go further into practice patterns. We are not suggesting that radiologists should be the only physicians allowed to perform and interpret X-ray examinations. But we are suggesting that others who undertake such examinations should be willing and able to demonstrate some level of competence.

The ACR feels that it has been carrying out a basic professional responsibility. on which is not diminished by growing federal programs. It is noteworthy that to a commendable extent in these radiation protection efforts, professional and public efforts have been coordinated and integrated. It would now be difficult to point to any radiation protection effort and say that it was entirely a College effort without BRH participation and support and conversely to identify a BRH educational effort which did not have College cooperation. We feel that a continuing professional initiative is productive and must be maintained.

Question 10. What is the current "state of the art" in diagnostic X-ray equipment? How much could patient exposure be reduced if modern X-ray equipment were to replace the existing inventory?

Answer. We have suggested in other parts of our responses that the "state of the art" in diagnostic radiology is healthy and productive. Advances in the past 30 years have led to routine use of electronic image intensification and television systems which make possible an increase in the fluoroscopic image brightness of 3,000 to 5,000 times. This permits an image which can be viewed or recorded in normal light. It also allows X-ray motion pictures to be taken at safe radiation levels. Other advances have led to shortlived radioisotopes, such as technetium 99m, with a six hour half-life which allows better nuclear imaging with less accumulated dose to the patient. We have seen the introduction of ultrasonic pulsing equipment capable of producing diagnostic images without ionizing radiation. We have experiments with thermography, the body's own pattern on heat emissions. In recent years, we have seen the introduction of the computerized tomographic scanner, possibly the most revolutionary development since discovery of the X-ray itself. We have learned to use computers in various other ways to enhance and analyze images. We have adapted signal transmission and detection methods devised for space exploration to medical needs.

As mentioned, the advent of diagnostic performance standards as promulgated by FDA in 1974 has resulted in changes in basic diagnostic X-ray units to improve the fidelity of the energy output and to limit the extent of the X-ray beam at the film or other image receptor. The attention to beam limitation stemmed from an estimate in the 1964 PHS X-ray Exposure Study that if all X-ray exposures had been limited in area to the size and shape of X-ray film holders or fluoroscopic screens, some one third of total radiation exposure could have been avoided.

We might cite the recent introduction of "rare earth" intensifying screens which are advertised to allow shorter exposure times without loss of image detail, thus reducing radiation exposure.

Then we must correct an implication in your question that most current X-ray equipment produces excessive X-ray exposures and fails to meet the 1974 performance standards. In point of fact, an increasing portion of existing X-ray equipment is now incompliance with those standards. Some 42 percent of all X-ray examinations performed in this country are done on systems which are less than five years old. Some 70 percent of the examinations are done on systems less than 10 years old. Most radiologists try to replace equipment on five or seven year cycles. Some pieces of specialized equipment and certain parts of the system may be older and still be capable of excellent performance. It was always possible for a proficient technologist to limit X-ray beams carefully and to perform examinations with minimal exposure to patients, or without performance standards imposed upon the equipment.

Thus, we cannot quantify a reduction in radiation exposure which might result from that time when essentially all equipment will be in compliance with the 1974 standards. All certified replacement elements for pre-existing machines must be in compliance after 1979, for example. Unless there are significant technical breakthroughs, we doubt that there will be more than a marginal reduction. We think far greater reductions can be achieved by attention to quality assurance techniques, to efficacy considerations in patient selection and to physician education programs.

Senator STEVENSON. The hearing is adjourned.

[Whereupon, at 1 p.m., the hearing was adjourned, to reconvene at 10 a.m., Monday, June 27, 1977.]

RADIATION HEALTH AND SAFETY

MONDAY, JUNE 27, 1977

U.S. Senate,
Committee on Commerce, Science, and Transportation,
Washington, D.C.

The committee met at 10:05 a.m. in room 5110 of the Dirksen Senate Office Building; Hon. Wendell H. Ford presiding.

OPENING STATEMENT BY SENATOR FORD

Senator Ford. Good morning, ladies and gentlemen. In the first 2 days of these hearings, the committee has heard some extremely disturbing testimony. The FDA estimates that there may be 40,000 to 50,000 operators of medical X-ray machines who have not had appropriate training or been certified by relevant professional groups—and who, presumably, could walk in off the streets and start pushing buttons. To correct this state of affairs, the General Accounting Office recommended that FDA work more vigorously with the States to insure an X-ray operator's competency.

The FDA is required to report annually to the Congress recommending legislative action. Yet, this agency, the FDA, has never addressed this issue in its annual report. Since every man, woman, and child in the country is potentially at risk from unnecessary exposure, I can assure you that this committee will monitor the FDA's position on this issue. At the present time, only four States—including my State of Kentucky—and Puerto Rico have X-ray operator credentialing programs. Senator Randolph has introduced legislation which would attempt to remedy this situation.

Second, the FDA indicates that the problem of improperly maintained and calibrated machines is significant. No one seems to know how much unnecessary radiation is emitted from machines manufactured or assembled before 1974. But the committee has heard that some studies report exposure at dangerously high and medically unnecessary levels. Furthermore, 30 to 50 percent of the new machines do not appear to meet the standards FDA prescribed in 1974.

Third, we have heard that the current malpractice climate and so-called defensive medicine contributes to many physicians' tendency to prescribe unnecessary X-rays.

A study performed at the University of Washington Hospital reported that X-ray examinations of skulls were reduced 40 percent when appropriate criteria for recommending these examinations were followed. The committee hopes that additional studies for other forms of X-ray examinations such as mammography are forthcoming.

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While the public's understanding of the effects of unnecessary ionizing radiation the increased, controversy as to the effects of ionizing radiation at low levels continues among the scientific community. All of these problems should be of immediate concern to the medical profession, the consumer, the taxpayer, and the Congress.

Today the committee expects to be informed of the research conducted on the possible effects of nonionizing radiation on human health and the environment. Preliminary work undertaken by the committee indicates that this is a highly controversial subject.

Today we will hear from several experts from the military and State Department and learn their views on the present state of knowledge, the research currently being conducted, and their views on the adequacy of present standards.

Unfortunately, several experts who have previously testified as to findings of potentially hazardous effects are unable to testify today. Nevertheless, the committee is interested in hearing from all interested parties, and if necessary, supplementary hearings on these issues will be held at a later time.

The first witness this morning will be Herbert Pollack, M.D., Ph. D., Office of Medical Services, Department of State, Washington, D.C.

STATEMENT OF HERBERT P. POLLACK, M.D., Ph. D., OFFICE OF MEDICAL SERVICES, DEPARTMENT OF STATE, WASHINGTON, D.C.

Dr. POLLACK. Thank you.

Mr. Chairman, members of the committee, your letter of invitation stated that you were particularly interested in receiving a brief summary of the Russian irradiation of the Moscow Embassy and a brief discussion of the study to be performed by the Johns Hopkins University. In addition, you continued, "The committee would appreciate receiving my views on the current knowledge of and research being conducted on the effects of microwave radiation."

These are two distinctly separate topics, and I will leave it to the chairman's discretion as to whether he wants to ask questions on the Moscow situation at the completion of that part of the presentation before going on to the discussion of the second topic. I would, in fact, prefer this procedure.

Your letter of invitation was addressed to me directly and I shall respond in that vein. My background in the academic world is seen by my title of professor emeritus at George Washington University. I am an independent medical consultant who has been associated with microwave bioeffects programs for over 15 years. Because of this background, I am a charter member of the Electromagnetic Radiation Management Advisory Council (ERMAC) and continue to serve on this Council.

I am not a career employee of the State Department but an independent consultant. The views that I express are my own and not necessarily those of the State Department.

I am in hopes of clearing up much confusion and misinformation about this situation.

In the early 1960's, the Advanced Research Projects Agency of the Department of Defense put a requirement on IDA to review the then current status of the biomedical effects of microwave radiation. Being the only medical man in the institute, the requirement was placed on my desk. My life has not been the same since. From the very first look at the situation it was apparent that there was an abundance of Soviet literature in the field which was difficult to interpret. A study was contracted to collect and review all relevant Soviet publications.

About that time, the then "secret" story of the microwave radiation of the U.S. Embassy in Moscow was revealed to us. Although it seemed highly unlikely in view of the signal characteristics but in view of the backdrop of the Soviet publications and in order to leave no possible stone unturned, amongst the list of possible reasons why the Soviets were carrying out this activity was the question as to the effects on man. With this question in mind, the Department of Defense developed the Pandora program, which basically was to expose monkeys—trained in certain procedures—to a synthetic Moscow signal, much stronger than the actual one in hopes of speeding up any effects, and then to see if this exposure altered their learned behavior. There were many problems with this experiment, but the final conclusion of the review committee was that under the conditions of the experiment there were no observable effects on the behavior pattern of the irradiated monkeys.

Now to get back to the actual story of the Moscow signal. While it is believed that the signal may have existed from time to time as early as 1953, it was not until the early 1960's that the State Department had the appropriate equipment on site to adequately verify and begin to characterize the signals' parameters. By early 1963 a recorder was monitoring the presence or absence of the signal on essentially a 24-hour basis. The maximum level of the incident radiation was less than 5 microwatts per square centimeter.

To achieve maximum exposure an individual would have to stand in front of an open window in the strongest part of the beam for all of the time the microwaves were being transmitted. It is evident that nobody had maximum exposure. As a matter of fact, the Moscow wind is very cold and I question whether people even opened their windows.

These radio waves originated from a single source west of the chancery and were focused on the upper floors of the central portion of the building. The records show that the responsible officials of the Department of State including the successive directors of medical services from the very beginning investigated the possible health effects from exposure to this level of microwave. Consultant medical experts assured them of safety, and medical record reviews supported their point of view. Since no known health hazards were involved, staff were not officially informed of the presence of these "waves" at that time. I was one of the medical experts consulted at that time by the then Medical Director, Dr. Woodward. His memo to that effect is still on file.

I will give the specific frequencies and other details so that these are available to anyone who wants to assess the situation. The original signal which continued until May 1975, consisted of usually multiple microwave signals, transmitted in any one of three different modes. These were in the range from 2.56 to 4.1 mega hertz, with occasional variations. The modes were typically assumed in sequence, with each mode being on the air no more than about 6 hours and the signal—all three modes in sequence—was never transmitted for more than about 48 hours continuously. The radiation level between August 1963 to May 1975 remained at approximately 5 microwatts per square centimeter at the strongest point of the beam on the west face of the Embassy building. Over a 1-year period this signal was on the air about one-third of the time.

In January 1973, another Moscow signal similar to the first one was detected. These transmissions were discontinued on March 2, 1973, and reappeared briefly on February 1, 1974. Most recently, on May 28, 1975, the latter signal was again redetected.

This signal originated from the east, whereas the first signal source was from the west. The newer signal is an unevenly distributed, wideband, noise-modulated, microwave transmission. The second mode expanded the frequency coverage from approximately 0.6 to 9.5 gigahertz. In August 1975, another signal originating from the south was detected. These two signals displayed equivalent spectral modes and have been present almost daily since that time.

To monitor these signals and determine trends in radio frequency power levels and activity patterns, both signals are continually recorded. The monitor system records equivalent energy levels in discrete bands. Initially their activity averaged about 10 hours per day and for several months increased to a maximum of 18 and 20 hours a day.

Since February 1976, the activity periods have decreased to the present average, typically about 8.5 hours a day during the work week with only minimal activity on weekends.

Present modal power can be separated into the following general frequency bands:

Mode I, 0.6 to 2.2 gigahertz.
Mode II, 1.8 to 3.8 gigahertz.
Mode III, 4 gigahertz and above.

Modes II and III are the most often observed modes for both the east and south signal sources. Both signals had originally utilized mode I. At present the southern source transmits in mode I, II, and III simultaneously and only in 30 minutes to 1 hour segments.

The technical evaluation of the signal for potential health hazard characteristics was concerned with identifying the physical parameters of the RF signal for discernible modulation, pulse train content, and trends in RF levels. When the source of the radiation shifted from the west to the east and was supplemented in August 1975 by another signal from the south, the resultant maximum incident radiation was measured to be as high as at 18 microwatts/cm^2 at times. Pulsing or instability of the signal appeared for a while—in contrast to the continuous wave present since the beginning. This combination of circumstances resulted in a reassessment of the situation at that time.

A complete review of the medical records of the staff and their dependents was repeated at this time. This review in December 1975 again resulted in finding only the usual health problems of a small population group. The decision was made to brief the officers and staff and dependents about the existence of these microwave nonionizing radiations. The incident radiation at its maximum did exceed the Soviet occupational standard of 10 microwatts/cm^2, though—and please remember this—it was far below the United States and Western European standards which are 1,000 times higher.

It was decided that installing protective screening would attenuate the radiation intensity to miniscule levels within the chancery, thus attempting to alleviate the anxiety which might arise from the knowledge of the presence of the signals. I reemphasize that at no time has there been any evidence of health problems related to these very low levels of nonionizing radiation.

The screening was installed during the period of escalation of the intensity of the incident radiation purely as a prophylactic measure as we did not know how high the Soviets would go. It should be recalled that any incident radiation above the Soviet occupational standard was objected to by Embassy personnel regardless of the U.S. standard. As I will point out later, the Soviets are currently reassessing their standards. After the screening was installed, the Soviets reduced the intensity to about the 2 microwatt/cm^2 level inside the building—and the screens reduced the inside level to less than one-tenth of that value.

In view of expressed concerns about possible effects of exposure to microwaves, it was decided to support a biostatistical epidemiological study of the staff and their dependents who had worked or lived in the Embassy since 1953 even though the focused beam was first identified in 1962. For comparison, employees and their dependents from some of our other Embassies in Eastern Europe also were to be studied. It is to be expected that such an epidemiological study will bring out any differences in health and longevity. It may be possible to differentiate radiation effects, if any, from other environmental factors. Our other Eastern European Embassies have not had any radiation to the best of our knowledge. They have been checked.

A contract for such a study was signed with the Johns Hopkins University School of Public Health, to be carried out in the Department of Epidemiology under the general guidance of Prof. Abraham Lilienfeld. Such an epidemiological study is confronted with many administrative problems such as the difficulty in locating persons who have resigned and are not on the pension lists—FSO's are not on social security but have their own retirement system.

The military attachés, the marine guards, the Agriculture Department attachés, the USIA personnel, all have different personnel record systems. Each one has to be learned before we can locate the personnel assigned to Moscow. In any event, these problems are being solved slowly but surely, and by April 1978 is it hoped that a final report will be received. This report will be made available to any and all interested parties. It will not be kept classified.

One advantage of this study over others is that:

In the Moscow Embassy, owing to the 24-hour constant recording of measurements of the radiation locations and levels, it is possible to make a good estimate of the maximum microwave radiation to which an individual may have been exposed since 1962. Prior to that time, the assessment would be very gross. None of the remote apartments or the Spaso house have been irradiated. In Moscow about half of the personnel live in apartment houses apart from the chancery. About half of them live within the chancery. Within the chancery complex including the two wings, the radiation was focused above the sixth floor, and from 1953 to May 1975 was limited to the west facade. The measurements indicated that the radiation was not uniformly distributed and varied considerably even in these areas. Fortunately, we have records of the variations.

From June 1975 to date, the radiation has been directed at the south and east facades. By locating the work area—office—of the staff person, and the living quarters—whether at the chancery and which floor and side of the building, or in an apartment away from the chancery—there is enough information to estimate the levels of radiation, if any. The numbers of those who encountered maximum Moscow radiation are small, but if there was any impact on health, it should be seen in the statistics developed by the Johns Hopkins study.

Since early February 1976 and through the present time, members of the staff of the American Embassy in Moscow and their dependents have voluntarily submitted for serial blood counts. The counts and duplicate smears have been evaluated in Washington, D.C., by an independent laboratory as well as by our laboratory in Moscow. The original purpose of this program was to see if serial blood counts could be used as an indicator of pending health problems.

A review of the blood counts showed that about one-third of the people, regardless of place of work, residence, or date of arrival in Moscow, demonstrated a benign, mildly elevated lymphocyte count compared to several hunderd Foreign Service personnel who had come through Washington from other posts. Foreign Service personnel are subject to the same type of vaccination procedures. We had to compare with those people who had been essentially through the same procedures. The absolute counts as we obtained them were only slightly beyond a broad range of variations found around the world.

There have been no medical ill effects observed in individuals whose lymphocyte counts have been elevated. The condition disappears after departure from Moscow.

The elevated lymphocyte count noted is similar to blood changes seen during periods of acute viral infections. However, clinical symptoms of viral diseases have been variable in the community during the testing period, and this explanation thus cannot be confirmed. Other potential causes, such as pesticides, water contamination, giardiasis, et cetera, also have been closely evaluated as the cause of the elevated lymphocyte counts. There is the possibility that giardiasis may be the guilty party.

To analyze any possible relationship to microwaves, the blood counts were grouped into the following categories:

A. People who were working and living in Moscow prior to February 7, 1976—the date that radiation was reduced and the protective screening was installed. Subgroups were analyzed as follows: One, those living away from the chancery versus those living in it; two, those on the seventh floor and above, and those working and/or living below the seventh floor; three, those working on the seventh floor and above, and having west window exposure, and those having east and south exposure before May 21, 1975; and four, those having east and south exposure from May 1975 through February 7, 1976.

B. Those who arrived in Moscow after February 7, 1976, when radiation in the chancery was miniscule.

Analysis of the data showed no difference between any of the above groups.

Blood counts in children are quite different from those over 21 years of age. While we continue to check the blood counts of the infants and children, they are studied as a group independent of the adults because their counts are so different and fluctuate so widely.

Another group of people also were checked to evaluate long-term effects: the returnees from Moscow to Washington, D.C. It was found that all counts were at the same level as all other Foreign Service personnel after the returnees had been in the United States of America for over 2 weeks and up to 1 year. These tests proved that, whatever the cause, the lymphocyte elevation was completely reversible and benign. We have further evidence to that more recently.

In an effort to confirm further that the observed phenomenon is a Moscow-wide anomaly rather than confined to Embassy personnel, we have offered to perform routine blood testing on American and other nationals living and working in Moscow not associated with the U.S. Embassy.

Before leaving the Moscow story, there is one more ghost I would like to lay low. There have been allegations to the effect that many people have been evacuated from the Moscow Embassy for health reasons and in particular two children with a blood disease. In spite of the State Department releases to this effect, I have not seen a retraction of this story. The actual facts are as follows:

Two children in June of 1976 were brought back to the States with their parents because, in the course of the routine blood counts just described, their counts deviated somewhat from the rest of the people. You will recall I said earlier, children's counts fluctuate and are different. The Department of State paid for their air fares and expenses involved in consulting any physician of their choice. One child was examined very thoroughly at a major university-affiliated hospital. The complete examination failed to reveal any abnormality but only an excess fluctuation which can occur in children. The child was returned to Moscow and is in good health.

Examination of the other child revealed a congenital defect in the bone marrow which interfered with the production of one type of white blood cell. This early detection may well have saved her life as she was developing skin infections. As of a few weeks ago, she was well and happy.

In the course of the next several months, two other parents developed some anxiety about their children. The Department arranged at the parents' request for one of the children to go to the Mayo Clinic. There she was subjected to a large battery of tests from bone marrow to chromosomal studies. All were entirely negative. The child is back in Moscow very healthy. Another family home on leave took their children to a university hospital in Florida, arranged for by the Medical Division of the State Department. Again, the extensive examinations were negative.

In conclusion, I repeat that to date there have not been established any radiation-related health problems in the personnel who have served in the U.S. Embassy in Moscow. If there are any effects associated with that environment for any reason which we have missed, we expect the Johns Hopkins study to show them up.

Mr. Chairman, may I submit to questions on the Moscow situation before proceeding?

Senator FORD. It will be all right with me, Dr. Pollack.

I have a few questions on Project Pandora which you have said turned up no observable effects on monkeys exposed to the simulated Moscow signal. As I understand from the unclassified documents which I have seen, preliminary analyses led analysts to believe that the signal altered primate behavior and the studies of the brain suggested some energies were damaging to the tissue.

Later analysis refuted these reports. But I am curious. Why was the project classified?

Dr. POLLACK. Because the question of alarm. Of course, I didn't classify it. That was classified by DOD. Perhaps I shouldn't speak for DOD, who did the classification. I was merely one of the workers. It was my understanding this was kept classified because they did not want to create any panic or any alarm in the personnel in Moscow who had not been briefed as to the presence of the waves.

Senator FORD. What were the problems associated with the research design?

Dr. POLLACK. The problem was basically in establishing a baseline, which the personnel did not carry out successfully in continuity. The baseline was changed. Therefore, the readings were very difficult to interpret. You made a statement that the initial findings suggested alterations. I would suggest that you look at the final paragraph. That is a quote from the minutes of the first meeting of the Pandora Review Committee. You will find in the final paragraph of those minutes a statement to the effect that the Committee would like before giving any opinion, to review the actual data itself rather than taking the verbal presentation of one of the laboratory workers. This is in the minutes per se.

That statement that there were effects came from the verbal presentation of one of the workers and not the final opinion of the Committee. The Committee subjected the data to extensive analysis, as you will see, as part of the Pandora report which was sent to you. There is an entire appendix by Dr. Kubis on the statistical analysis. From this, the Committee drew its conclusions that there were no observable effects.

Senator FORD. Well, Doctor, we understand and have seen the Committee's report. Why were the major reports containing useful data destroyed?

Dr. POLLACK. I beg your pardon, sir?

Senator FORD. The actual data that the Committee studied we understand is not available.

Dr. POLLACK. No, sir. That is not available.

Senator FORD. What happened to it?

Dr. POLLACK. I don't know. That was in the hands of the Department of Defense and not in the hands of the Institute for Defense Analysis where I was associated. When we looked for them more recently, we found this data was no longer available. As you know, it is Government—Government files are not kept permanently. They are disposed of routinely from time to time.

Senator FORD. What is "routinely," Doctor?

Dr. POLLACK. What is that?

Senator FORD. What is "routinely filed or destroyed," not kept, burned? What is "routine"? Two years, five years, ten years?

Dr. POLLACK. I am not fully conversant with that, not being an administrative type of person and not being a full-time Government employee. All I know is what I have been told by the Government people that this is what their procedures are.

Senator FORD. I will get to the next witness then and see what they know about it.

Dr. POLLACK. Okay.

Senator FORD. Roughly how much did the project cost?

Dr. POLLACK. Pandora?

Senator FORD. Yes, sir.

Dr. POLLACK. I have to separate the equipment and facilities, which are still in use and which are now a national resource. This part of the expenditure, as I say, is still in use. It is a national resource. It exists at the Walter Reed Army Institute out at the—in the Maryland area. That part of the equipment, as I remember, ranges about $1.5 million, and as I say, is still in use.

The actual operating expenses, that ran to a matter of a few hundred thousand dollars over the course of the experiment.

Senator FORD. Have any of the findings or technologies developed in Pandora found their way into present unclassified research?

Dr. POLLACK. Yes indeed. There is no classified research going on at the present time to the best of my knowledge. I think I am fully aware of it at the facilities at the Walter Reed Army Institute for Research. As a matter of fact, they are rebuilding the equipment at this present moment. It has gotten into general use by all means. It is, as I said, a national resource.

Senator FORD. Can you speculate as to why the Soviet Government would want to irradiate the U.S. embassy in Moscow?

Dr. POLLACK. As I said, we have a whole laundry list of possibilities. I just don't know why they are doing it.

Senator FORD. Do you want to give a few reasons from your laundry list?

Dr. POLLACK. Mr. Chairman, I would prefer not to because my experience is in the biomedical field. I don't want to get outside of that competence at this type of hearing.

Senator FORD. Well, you said you were here on your own. You have been involved in it. You might be able to speculate a little, couldn't you? You said you had a long laundry list. Apparently you have seen it.

Dr. POLLACK. Yes.

Well, the reasons go anything from basically related to intelligence problems, I presume. At least that would be the evident reason.

Senator FORD. Do we use anything like that? The United States?

Dr. POLLACK. No, sir, we do not. We do not have any positive microwave emanation techniques of the type that the Soviets are using here. We know about them. We can analyze them. To the best of my knowledge, they are not in use.

Senator FORD. You said the level of microwave radiation, I think, to which the employees and their dependents in the Embassy in Moscow were exposed, is not harmful. Of course, you said that you installed the screens which, in case the intensity of the signal were increased, would provide protection. With the screen installed the intensity was reduced. Then why did you instigate the Johns Hopkins study?

Dr. POLLACK. Because of the questions that have been raised and because of the anxieties that have been manifested in the reactions of many of the personnel who were on the staff, the Embassy staff over the period of time that the microwaves were in effect. They have written many letters in. It is difficult to convince them directly of the harmlessness of the levels to which they were exposed. As I pointed out, we can tell you, generally speaking, within a very small range to which levels they were exposed at any time.

So to have on definite record a positive study that would answer their questions, we have instituted the Johns Hopkins study, which will bring out anything that we may possibly have missed.

Senator FORD. Let me ask you this question. Why was the decision finally made to brief the personnel in the Embassy in Moscow, about the existence of microwave irradiation of the Embassy? Why did the State Department behave differently in this situation than it did in the 1960's when it decided not to apprise Embassy personnel of the microwave situation?

Dr. POLLACK. The levels of microwave radiation in the 1960's were minuscule, as we pointed out, a maximum of 5 microwatts. As I said, in order to achieve maximum, you had to stand undressed in front of an open window practically all day at one point in the beam. So that the rest of them were receiving an average of 1 to 2 microwatts over a period of several hours.

When the Soviets started escalating and pulsing, then we were in the dark as to just what their direction of activities was going to be, and it was thought it would be a much safer procedure to be prepared if the Soviets were going to get drastic in their radiation levels, so the screening was put in at that time. As I pointed out, it was prophylactic in anticipation or to prevent the possibility of damage from elevated levels and also because the anxiety level of the people in Moscow, who were thoroughly familiar with the 10 microwatt standard of the occupational standard of the Soviets, did not want to be exposed to anything over the Soviet standards in spite of the fact that our standards are 1,000 times higher.

So we had to do something to protect them from this anxiety state, if you want to call it that.

Senator FORD. ERMAC has recommended conducting epidemiological studies but as you noted such studies pose horrendous problems. You queried, "What are the end points, what are the health effects to look for?"

Dr. POLLACK. Yes; that is in the second part of the testimony. I intend to cover that.

Senator FORD. I thought that was in the first part. We will get to that then.

Dr. POLLACK. I pointed out in the first part, Mr. Chairman, that the Moscow situation was probably a little bit easier to handle than any of the large-scale epidemiological studies in this country because we had defined parameters and excellent estimates of the radiation to which the people were exposed. We had the time, the duration, the living, et cetera. These are problems which will come up in further discussions on the epidemiological studies potential in this country.

Senator FORD. You say that responsible officials from the very beginning investigated the possible health effects of the exposure to microwaves and that consultant medical experts assured them of safety. You also note that the Soviet literature was abundant, and I quote you, "But difficult to interpret." On what basis were these assurances of safety given?

Dr. POLLACK. On the basis of health record, the examinations, and on the basis of the experimental work in this country. Basically, it was on the health records and physical examinations of the people per se in which, as I pointed out, I participated as early as 1964.

Senator FORD. When were the assurances given? In 1963?

Dr. POLLACK. Well, it would have been about—well, the question was raised in 1963 and reviewed, and the detailed studies were started about 1964; yes.

The levels were so low that there wasn't any pressure; 1 or 2 microwatt exposures, sir, is what you are getting here sitting here right now.

Senator FORD. Better turn the lights off then, hadn't we?

Dr. POLLACK. Could be. I believe some of your earlier testimony that I heard, EPA reported, for instance, the Sears Tower was getting 60 microwatts and that's 30 times greater than what they were getting in Moscow.

In this country we have a few areas where the levels are higher, but we will go into that in the second part of the testimony.

Senator FORD. You say in 1975, with the addition of a new signal originating from the South, pulsating, a reassessment of the situation resulted. Why? What was so peculiar about the situation in 1975 that a decision was made to inform the staff after keeping information from them for the previous 12 to 22 years?

Dr. POLLACK. At that time the levels were escalating from the low levels of 5 microwatts. It had gone up to 18 microwatts. The signal was beginning—was pulsing, and a pulse signal was a much greater biological activity than the so-called constant wave. In view of the rising or the incremental increases, it was decided to brief the people to let them know, because the screening was going up to protect them. You couldn't put screening up without letting the people know why it was going up. As I say, this was a prophylactic measure. If we hadn't done so, we would have been remiss.

Senator FORD. Doctor, was not the real motivation for briefing the Embassy personnel the fear of public exposure from the Moscow radiation situation?

Dr. POLLACK. I do not know, sir. I was not privy to those discussions in Washington. I was in Moscow at that time.

Senator FORD. Do you have any sense about the motivation, any gut reaction to it?

Dr. POLLACK. The reason for the briefing?

Senator FORD. Yes, sir.

Dr. POLLACK. Well, as I just pointed out, the decision to put up the screening had been made. It was obvious that the people had to know why screening was going up. And so they were briefed to let them know why screening was going up.

I repeat again, the screening was a prophylactic which we would have been very remiss if we had not carried out.

Senator FORD. Is it your opinion, then, that from observations and studies done on Embassy personnel that they had exhibited no effects which can be attributed to microwaves?

Dr. POLLACK. No physical health effects have been demonstrated to date; none that we have been able to find. I personally spent several weeks in Moscow reviewing all of the medical records of these people, and I have reviewed the blood counts, too. I can assure you that my professional reputation is at stake on this. I am not loath to put my reputation at stake on this one.

Senator FORD. Are there any behavioral effects associated with microwave radiation?

Dr. POLLACK. Behavioral?

Senator FORD. Yes, sir.

Dr. POLLACK. Yes, of course. Of course, there are behavioral effects. These are, as we have seen them, a normal anxiety state of the unknown. Mind you, these people who are not familiar with microwaves, this is something coming through the air which is unknown. They are told about it. It is very difficult for them to grasp the concept, particularly when the word "radiation" was used.

The word "radiation" is a bad word. This is what has provoked so much of the misunderstandings and controversy, because the word "radiation" is a generic term for the transmission of energy through space without the use of hardware or hard substance.

Now, ionizing radiation, which is what people were accustomed to hearing about, is confused almost immediately with nonionizing radiation. Most of the questions we had thrown at us were related to the Hiroshima and Nagasaki experiences of radiation. I can assure you, sir, that there is no relationship.

As you have heard in previous testimony, the levels of energy in the microwave are quantum, a billionth less than the level of energy, less than 1 quantom of ionizing radiation.

These just are two entirely different things.

Senator FORD. Doctor, do you want to get on to the other portion of your testimony?

Dr. POLLACK. At your pleasure.

Now, let me shift gears and try to answer your second question. Again, I repeat, as you know, I have been a member of ERMAC since it was convened. For over 50 years I have had a broad interest in the impact of environmental conditions on health. For the last 15 years this interest has been focused on the health effects of nonionizing radiation. Over this long period of time I have served on many advisory councils, boards of directors of voluntary health agencies, as an individual consultant, and in other similar capacities. I say this by way of background.

First, I will give my reaction to what I have heard in the course of these hearings and to other questions which have been posed. There has been a good deal of discussion about the differences between Eastern and Western safety standards and research. In fact, you have heard that the U.S. and Western European scientists disregarded the published research on nonionizing radiation from the Eastern European countries. Many U.S. and Western investigators have carefully studied Soviet research and have written extensive reviews. The American journals have published translations of Soviet reviews.

We were not guilty of overlooking the Soviet work, but we were trying to be objective. Much of the Soviet research on nonionizing radiation has been criticized for its poor experimental design, lack of adequate controls, and drawing conclusions from inadequate evidence. Most important was that the information available to us from their publications was very limited. However, nobody was willing to dismiss offhand the work of the country who launched Sputnik or did such excellent work on biological effects in the field of ionizing radiation.

In fact, it has had a real influence on recommendation and current U.S. research program. Some of our early efforts and resources were diluted attempting to duplicate the Eastern European research. Their publications did not give the full story of their laboratory procedures; hence, it was impossible to duplicate them. Until recently there was very little direct contact with the Soviet scientists to bridge the gap.

In the Soviet system, there are at least three separate categories of laboratories and research workers in this field of health effects of nonionizing radiation: 1, industrial and public health; 2, the military; 3, other institutes of the academies of science, including the Academy of Medical Sciences.

Parenthetically, it can be said that the Soviet military are not bound by their current safety standards, but the U.S. military are bound by ours. This is important to bear in mind if new standards are promulgated. It is difficult to imagine that the Soviet military could function effectively under the restrictive natures of their current limits. As a matter of fact, there is good evidence that the Soviets are currently reassessing the scientific basis for their current standards. The Institute of Biophysics under the Soviet Academy of Sciences is undertaking a research program for this purpose. Recently two U.S. scientists were invited to participate in a seminar at this institute devoted to this subject.

Current U.S. research is two-pronged: 1, the theoretical and experimental search for mechanisms; 2, the pragmatic—studying effects directly on the intact animal and man.

A complete understanding of mechanisms of interaction could facilitate our ability to predict biological effects. There is adequate precedence for the pragmatic approach—as, for example, in the use of penicillin. This drug was used successfully for 20 years before the mechanism of its action was understood. There is evidence now that research in this area is gaining momentum. The development of methodology and instrumentation for measuring absorbed energy instead of just using incident radiation is opening new vistas in the laboratory. This approach may serve several purposes: (a) a method of finding the mechanism of interaction, (b) a method of translating findings from animals to man, (c) relating external to internal fields, (d) relating a known amount of absorbed energy to an observed response.

Other developments involve the renewed interest in, and acceptance of, the concept of specific frequency and resonance phenomena, including "hot spots" and their corollary that bioeffects are frequency-dependent.

There are fields of research that have not been explored adequately as yet. In its early meetings, one of the recommendations of the ERMAC was to conduct epidemiological studies on the effects of nonionizing radiation. Last year OTP requested ERMAC to give the topic further consideration. Discussions were held with a number of knowledgeable groups and individuals. The problems, however, are horrendous; they focus in two main areas:

I. What are the end points? What are the health effects to look for? At present these have not been established, and this makes the design most difficult.

II. The other is even more difficult—defining the exposure levels of people and identifying potential groups for study. For example, as EPA has reported, environmental levels are generally very low and vary widely. Furthermore, they are influenced by such factors as terrain, construction material such as metal siding and insulation, et cetera. In addition, there is the mobility of the American population to consider. Finally, there are other multiple environmental factors, such as air quality, to be taken into account. We continue to believe that such studies are important. Further effort must be made to design useful research in this area involving special and specific occupational groups.

Another part of this problem which as a physician/physiologist has disturbed me a great deal is the use of the "average field strength" as the indicator of exposure over the wide range of frequencies. This is an engineering term. In measuring incident radiation, many portable instruments integrate power densities of multiple frequencies into a single sum. Furthermore, with modulated—pulsed—radiations, they will average over time the peaks and the valleys. Thus we may read—average over field strength is 0.1 mW/cm^2, when there may be a peak of 350 mW/cm^2. Sometimes the peaks are missed because the instrument lag time is too great to pick up very fast pulsed (nanosecond) radiation. While peaks frequently are in minute fractions of a second, their biological effects have not been studied adequately. I am uneasy about the widespread reliance on average field strength as an adequate measure of exposure, but then I am a physician and not a physicist.

I note there is talk of creating one agency for research and regulation of all radiations. I believe the concept of a single agency has many scientific and administrative drawbacks. You have heard, and undoubtedly will hear more, about the several ongoing research programs. These are basically oriented toward the mission of each of the agencies supporting the programs.

It is difficult to see one single agency carrying out sufficient research for the many frequencies and other EMR conditions which will meet the needs of all the agencies involved at the same time. Research under a single agency can lead to a lack of flexibility in new approaches and scientific innovation which are badly needed in this field.

The progress to date in this field in this country is due in large part to the cooperative attitudes of the investigators from various institutes. In ERMAC, interagency and scientific meetings have seen a free interchange of information and an exchange of experiences.

Progress in research is dependent primarily on people, well trained, informed, and supported adequately. I place the primary focus on the individual researcher. The people we need are those with innovative ideas and the gift of deductive thinking.

Let me illustrate this latter point: An obscure medical student in Germany in the mid-1800's carried out a routine experiment which had been done by hundreds before. He removed the pancreas of a dog to study its digestive functions. Minkowski, however, noted that the urine of this dog attracted swarms of flies. This simple observation laid the basis for our modern concepts of diabetes and led directly eventually to the isolation of insulin.

Research today in nonionizing radiation requires a little more than the simple laboratories of yesteryear. The equipment for generating the radiation, the devices for measuring, and the precautions and controls in exposing animals are elaborate and expensive. However, the keystone of the effort is still the scientists, albeit a multidisciplinary team.

The understanding of the biomedical effects of nonionizing electromagnetic radiation is a developing field. It is wide open. It needs a multiplicity of inputs from a variety of disciplines. The physicist and engineers have dominated the field as the physics of nonionizing radiation is a very complex subject. Now that the emphasis is shifting to the biological and medical effects, the biologists, physiologists, and physicians must enter the field. The living man and animal react very differently than the inert material which engineers are accustomed to handle. The living organism has compensatory and feedback mechanisms which allow them to adapt to environmental changes. Thus a piece of meat in a microwave oven will accumulate heat at a predictable rate; on the other hand, a rise in body temperature in a living animal is a poor guide to the amount of absorbed energy from microwave exposure. The homeostatic mechanisms play their part just as soon as there is a change in the environment and within reasonable limits permit the organism to adjust. These same mechanisms come into consideration in comparing long-term chronic exposures to acute ones. The necessity for the input of the environmental physiologist is self-evident. Developing a working knowledge of the interdisciplinary aspects as well as the communication problems is a long and arduous process. I know—I have had to learn the hard way.

You ask for recommendations for future research. It is easy enough to make up a "laundry list" of necessary work. This has been done by the ERMAC and many other groups and individuals. The high priorities for research should include both pragmatic studies for effects and theoretical and experimental investigations for mechanisms. The theoretical and experimental studies should be carried out to insure complete understanding of all mechanisms of interactions between electromagnetic fields and living systems. The pragmatic studies should emphasize chronic low-level exposure—less than 10 milliwatts per centimeter squared, impact of peak powers, and epidemiological studies of selected groups of people exposed to various levels of microwave energy.

The current coordination mechanism is working successfully, and to change it would disrupt the ongoing programs and seriously delay the progress, as would the formation of a new consolidated agency. The effectiveness of this coordination is largely due to the open, supportive, and noncompetitive role of an office at the level of the Executive Office of the President, and the dedicated efforts of the personnel on this task.

Nonionizing radiation research is coming into its own. It is beginning to attract well trained scientists in the biological as well as the physical disciplines. There is no present crisis of environmental pollution insofar as health is concerned from this modality. Any necessary regulatory action must be based on research findings and demonstrated need. It is important that we do not stifle this emerging field by administrative controls set in the concrete of a rigid bureaucracy. You have inferred the urgent need for answers to the question of hazards. The most effective way of speeding up the research program is to create a climate which will attract scientists into the field and then support their work.

Senator FORD. Just a couple of brief questions, Doctor, on your second statement, or the second portion of your statement.

I believe you said that nobody was willing to dismiss offhand the work of a country who could launch Sputnik. I believe by your own account, 1963 was the first time anyone considered examining the abundant Soviet literature, which presumably was amassed during the 1950's. The fact that you had to contract for a study to collect and review all of the Soviets publications indicates that, in fact, that research had at least been ignored, if not dismissed. In 1963, the Tri-Service program, which came up with the 10 milliwatt standard, had been completed.

Presumably the military researchers had not looked at the Soviet work. Do you think present American researchers are paying more attention to their Soviet counterparts?

Dr. POLLACK. Sir, may I correct a misunderstanding which I think exists there? There is evidence in the Tri-Service—in the records of the Tri-Service meetings that the Soviet literature was taken into consideration. When I say that we started our interests, that is because that was the time I was drawn into the field. I was not discussing what had occurred previously. I was expressing my own experiences, and the experiences of my associates.

The contract for the study of the Soviet literature that I discussed or mentioned was let because this was the time we were drawn into the field wholeheartedly. I repeat that there is evidence in the Tri-Service reports which came out in 1957, 1958, and 1959, that the Soviet literature was evaluated.

You must recall the Soviet safety standards were first set in 1958. The question of comparison of standards historically, then, originated from 1958, when the Eastern bloc, Eastern European countries, began to establish standards. And it was shortly thereafter that Miss Healer and I wrote a complete review of all the standards established around the world. That was the time we were invited in to discuss and review this matter.

Senator FORD. We have talked to Dr. Allen Frey, who just returned from Moscow, who discussed the Soviet's reassessment of their standards. Are U.S. standards being reevaluated?

Dr. POLLACK. They are under consideration and reassessment, yes. At all times they are being reviewed continuously.

Senator FORD. A continuous review?

Dr. POLLACK. Yes. The ERMAC people periodically review the situation. The question of change in standards has been mentioned several times.

Senator FORD. Can you foresee any change in the U.S. standard?

Dr. POLLACK. Sir, as I said in my statement, standards must be set based upon experimental work and demonstrated needs. At the present time, there is no demonstrated need for the change, and when there is a demonstrated need, people are prepared, EPA has already said that they are prepared to reestablish or to redefine standards.

I believe they testified to that effect here last Thursday or Friday.

Senator FORD. Doctor, I do not believe I have any further questions. We appreciate you coming and spending so much time with us. We may have some further questions which we will submit to you in writing.

Dr. POLLACK. Thank you, sir.

[The following information was subsequently received for the record:]

DEPARTMENT OF STATE,
Washington, D.C., September 13, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, United States Senate.

DEAR MR. CHAIRMAN: Thank you very much for your letter of August 15. In response to the additional questions listed in your letter, summaries of reports are submitted as enclosures.

If I can be of any further service, please let me know.

Sincerely,

HERBERT POLLACK, M.D.
Medical Consultant
Office of Medical Services.

Enclosures:

1. Replies to 9 questions
2. Appendix A
3. Appendix B
4. Appendix C

Question 1. You have stated in your testimony that there were many problems with Project Pandora. You mentioned the difficulty in establishing a consistent baseline. Other than this cited problem, what were some of the other difficulties with the Project? Do you believe these difficulties were so serious as to render the experiment inconclusive?

Answer. Pandora was funded by Advanced Research Projects Agency (ARPA) in early 1965 for research to evaluate a threat which appeared to have strong behavioral and biomedical implications. Preliminary incomplete analysis of the in-house work at Walter Reed Army Institute for Research (WRAIR) encouraged the belief that this special non-ionizing microwave signal altered primate behavior. Preliminary extramural cytogenic and histological studies of brain suggested that comparable energies were damaging to tissue. Detailed analysis of the data and subsequent experiments failed to support these preliminary results.

The project, conducted at WRAIR and supported by ARPA of the Department of Defense, refers to 4.6 milliwatt level of incident radiation in the "synthetic" signal. This was "accelerated" testing and is very much higher than the actual Moscow signal which was approximately 5 microwatts maximum at that time.

The term "synthetic" as applied to the signal indicates that the signal was constructed for experimental laboratory purposes, not as an effort to precisely duplicate the radiation levels actually encountered in Moscow. The memo of January 14, 1969, entitled "Flash Report of Pandora Bizarre Briefing."[1] referred to a very preliminary flash report on the study given under stress. Two paragraphs later the memo stated that the study on reaction times was inconclusive. The final paragraph of that memo noted that the presentation was qualitative and suggested the data be prepared in a statistical format for better scientific evaluation. The panel which reviewed the study expressed the desire to examine the data in depth.

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[1] The unclassified minutes referred to are reproduced *infra.*

The minutes of the January 12, 1970 meeting shed additional light on this issue. Paragraph II of Section 1 of the minutes reviewed the preliminary analysis presented by Dr. Joseph Sharp which encouraged the belief that the synthetic signal altered primate behavior and that cytogenetic and histological studies suggested that comparable energies were damaging to tissues. The next paragraph referred to the Pandora Scientific Advisory Committee (SAC), which was appointed in 1968 to provide advice for the development of the research program. The Committee recognized that the interaction of electromagentic fields with living tissues is determined by a great many factors, and it is virtually impossible to draw any meaningful conclusion from the relationship between simple measurement of incident radiation and biologic effects in a test object. The statement is made, "In contrast to the initial analysis, the complete analysis concluded that if the synthetic signal had an effect on behavior, it was so modest as to be obscured by the effects of experimental procedural variations which were a result of the exploratory character of the early experimental program. Furthermore, continued extramural cytogenic studies did not confirm the earlier reports of changes of tissue exposed to the synthetic signal."

Section II of the January 12, 1970 memo explains why Sharp's earlier treatment of the data did not adequately demonstrate the differences defined previously. Paragraph II and the remaining sections of the memo provide further explanation of this discrepancy as well as additional pertinent evaluation of the data.

Section II of the report, containing the summary and recommendations, states in Paragraph A that ". . . since no clear and strong effects have become apparent with the Walter Reed Army Institute of Research (WRAIR) signal, the findings thus far can be regarded as negative."

The actual measured radiation in Moscow never was higher than 18 microwatts (or .0018 milliwatts) and then only for a limited time in a limited area.

The more recent development of the ability to measure internal electrical fields and absorbed power may enable the research workers to better understand reactions and translate animal reactions to man.

At the time of Pandora, we did try to determine any central nervous system effects on the crew of the carrier *Saratoga*. Details are in the Pandora files, a summary of which is given here.

April 21, 1969—Big Boy—No significant differences in psychological tests performed on apparently exposed and control group. Also, no apparently significant differences on genetic (leukocytes) and physical findings.

Detailed survey of on-board radiation levels revealed that levels were in most cases from 0.3 to 0.03 mw/cm^2 in no case greater than 1 mw/cm^2.

Pandora—August 12–13, 1969

1. Reaction time study

Shock avoidance—no difference

2. Multiple schedule for operant conditional primates

Two of five sessions—Data not interpreted because of equipment malfunction. Use of re-enforcement schedules which reward certain types of stoppages were recognized as contributing to work stoppage rather than the exposure to microwaves.

Question 2. Do you have any knowledge of any subsequent attempts by independent researchers or researchers within the military to create a similar test situation to verify or refute Pandora's results?

Answer. At present I know of no experiments to duplicate the "Pandora" using the multi-frequency Moscow signal. There are several experiments using single frequencies which relate to central nervous system and behavioral effects.

Question 3. You mentioned in your testimony that certain embassy personnel objected to incident levels of microwave radiation above the Soviet exposure standard. Please specify just which of the embassy personnel objected.

Answer. The most recent expression of objection was published in the *Foreign Service Journal*, Volume 54, No. 8, August 1977, Page 36, a copy of which is enclosed as Appendix A.

Question 4. In your prepared statement, you referred to the observation of various embassy personnel and stated that, "It was obvious that the observed changes in blood count bore no relationship to microwave radiation." Why was this obvious? Is it not possible that there may be a long latency period associated with such effects, and that they will show up in the future? Are you aware of any research programs currently underway to detect such delayed effects?

Answer. The statement that the blood count changes were not related to microwave radiation was based on the observations that the same changes were found in those who had arrived in Moscow after February 1976 when the radiation levels were minuscule as on those who had been there for two years. Also the same changes were found in those who lived away from the chancery and worked on the ground floor. This latter group did not receive any radiation.

The epidemiological study by the Johns Hopkins University group is designed to detect delayed effects.

Question 5. Do you believe that Johns Hopkins' epidemiological study will be able to conclusively answer questions such as those posed above?

Answer. The Johns Hopkins University study should be able to unearth delayed effects if there are any.

Question 6. Why is Walter Reed currently rebuilding the Project Pandora facilities? What unclassified research is being conducted at the Walter Reed facility?

Answer. The Walter Reed facility, as I stated, is now unclassified. It is being rebuilt and modernized and will be available to selected research groups. Currently, the facility is under repair and not operational. The animal facilities particularly are being modernized. The work of Dr. Albert at George Washington University for example utilized the Walter Reed exposure facilities.

Question 7. To the best of your knowledge, does the embassy in Moscow have any positive microwave emanating equipment which is used either for intelligence purposes or for "jamming" purposes?

Answer. I am not privy to any microwave emanating equipment in the Moscow Embassy beyond the normal communication systems. The times I have observed the electronic "sweeping" of the chancery for microwaves, I never saw any evidence of such emanation in the building except from a communications aerial and the extremely low frequency waves from the 50 cycle motors and electrical conduits.

Question 8. In your testimony, you indicate that there are horrendous problems with conducting any epidemiological study. Why then do you believe that the Johns Hopkins study will be determinative of whether or not the health problems incurred by Moscow embassy personnel were the result of exposure to microwave radiation?

Answer. In my testimony I was referring to epidemiological studies of general population groups. The problems of dosage calculations are most complex, i.e. mobility of population in and out of field; geography of area, hills, valley, etc.; presence of reflecting surfaces; use of aluminum vapor barrier insulation will reflect microwaves; aluminum siding of houses; age distribution; presence of air pollutants and other etiological factors. In Moscow there was constant recording of radiation over 24 hours since 1962. Enough data is available to give a good approximation of the radiation received by different groups. The mobility of the population is known so that the uncontrolled factors present in populations are controlled in the Moscow Embassy situation.

Question 9. During the hearing, you discussed possible causative factors of the elevated lymphocyte counts among embassy personnel. The 1976 OTP annual report noted similar effects related to nonionizing electromagnetic radiation. The OTP stated that such an effect was of interest because of the relationship to the body's total immune defense system. Are you aware of research that has been conducted since the publication of the OTP report or since the presentation of your testimony before this Committee? If so, please provide the Committee with appropriate citations to such studies. Are you aware of any research in which the possibility is explored that microwaves in and of themselves may not cause harm but that in conjunction with other environmental agents might prove harmful through their impact on the immune system? If so, specify.

Answer. There is abundant ongoing research to determine the influence of nonionizing radiation on the body's total immune defense systems. Appendix B is a very brief summary of nine relevant projects in this area. There are several more reports scheduled for the forthcoming URSI meeting on October 31-November 4, 1977. A copy of the seminar program is enclosed as Appendix C.

The synergistic effect of other environmental agents to microwave radiation is being researched now, especially ionizing radiation coupled with nonionizing radiation in the treatment of cancer. This is a new field and I have not seen as yet any final reports.

With the help of the Naval Medical Research Institute (NMRI) at Bethesda, the National Institutes of Health and the National Cancer Institute, we have carried out specific immunological and cell differentiation tests on 10 Moscow personnel to date. Surface markers for both T and B lymphocyte cells were quantified by several techniques. Mitogen stimulating studies were carried out as well as liver enzymes, human antibody, serum electrophoresis and immunoglobulin quantification.

The interpretation of the findings clearly indicated that these were not monoclonal in origin and hence definitely not pre-leukemic status and that hepatitis was not a factor. The elevation of IGA was considered significant in three subjects. This is usually an indication of an intestinal infection or infestation. Since giardia is so very common, the presumptive interpretation is that giardiasis may be responsible for the elevated lymphocyte count in one-third of the employees. Further work is being done to test for cytomegalovirus and Epstein-Barr virus as those may also be involved.

APPENDIX A

[Foreign Service Journal-Aug. 1977]

COMMITTEE ON EXTRAORDINARY DANGERS

During the past year the Committee focused on two main topics: (1) our policy with respect to terrorism and particularly how we deal with kidnapping and other threats against our employees abroad; and (2) the problem of the continued bombardment by the Soviet Union of our Embassy by microwave radiation.

(1) TERRORISM

AFSA continued to urge the Department of State to review the current policy towards terrorism and, specifically, to make the necessary changes which would better protect Americans subject to kidnapping or other terrorist threats abroad. A number of studies have been done by outside experts which are critical of the way in which the Department handles terrorist situations. We believe that a full evaluation should be made of these criticisms and necessary improvements implemented on our present policy. We hope to work with the new Administration toward this end in the coming months.

Some progress has been made on the terrorism issue. The CED pressed strongly to have the government take action against those countries that harbor, support, or release terrorists. In particular, AFSA was concerned about the punishment of a terrorist that attacked the US Embassy in Cyprus in 1974. The alleged at-
Unfortunately, the killers of our Ambassador to Lebanon and FSO Waring
tackers have been arrested and are now standing trial for their terrorist activities. Unfortunately, the killers of our Ambassador to Lebanon and FSO Waring remain, to the best of our knowledge, unpunished.

The Committee continues to urge perservance on the part of the United States government to bring to justice these individuals and to take action against any governments that support terrorists that threaten American employees abroad. It is our hope that we will be able to obtain from the new Administration support for a strong stand against terrorists and increased efforts to apprehend those who have attacked American employees abroad, together with appropriate assistance to the victims of terrorism.

(2) MOSCOW RADIATION BOMBARDMENT

AFSA has taken the position that there should be total cessation of beaming microwave radiation at the US Embassy in Moscow on the part of the Soviet Union. We have had a number of interviews with Department officials and made it clear where we stand on this matter. The Department of State has agreed with us that radiation should cease but has so far been unable to have it completely stopped. At AFSA's rging, the Department has undertaken an epidemiological study of American personnel in Moscow to determine whether or not there have been any adverse medical effects from radiation exposure. This study is being conducted by Johns Hopkins University, but it has experienced considerable delays and AFSA has been pressing for completion of the study as soon as possible since only after the results are known can we determine the exact degree of hazard to the health of Americans who were exposed to this radiation. The Committee is in regular contact with the Moscow Chapter with respect to actions AFSA should take with the Department to persuade the Soviets to cease totally the radiation.

* * * cans who were exposed to this radiation. The Committee is in regular contact with the Moscow Chapter with respect to actions AFSA should take with the Department to persuade the Soviets to cease totally the radiation attacks. At present these levels have been reduced from a maximum of 18 microwatts down to a fraction of 1 microwatt.

It is the view of AFSA that in the light of the unknown health effects of such exposure, all such radiation attacks should cease. In addition, there is a major problem with respect to the precedential question in that as a matter of principle, Foreign Service employees abroad should be immune from exposure to deliberate acts on the part of host governments which could endanger their health and well-being.

AFSA will continue to press the Department of State for the completion of the Johns Hopkins epidemiological study. We have nominated Dr. Lawrence Plumlee as our representative on the review committee to examine the efficacy of the study. Dr. Plumlee will also consult with AFSA with respect to this whole problem area. This is the first time that AFSA has had expert advice in this field from a highly regarded environmental scientist and doctor. We also will pursue the question of what medical rights American employees should have as a result of exposure to radiation in Moscow of which they were not informed. Finally, we will be working with our AFSA Chapter and with management officials with respect to what strategy we should pursue to get the Soviets to turn off all radiation in Moscow, which currently continues.

APPENDIX B

ELECTROMAGNETIC RADIATION MANAGEMENT ADVISORY COUNCIL AGENDA FOR WORKSHOP/SEMINAR ON NONIONIZING ELECTROMAGNETIC RADIATION EFFECTS ON IMMUNOLOGIC SYSTEMS AND RESPONSES

December 15, 1976, 8:30 AM. Office of Telecommunications Policy, 1800 G Street NW., Room 730, Washington, D.C.

MORNING

I. INTRODUCTORY OVERVIEW EXPOSITION AND DISCUSSION

Overview. Dr. Thomas P. Stossel, Chief, Oncology Division, Massachusetts General Hospital, Fruit Street, Boston, Mass.

Discussion.

Capt. Kenneth W. Sell, MC, USN, Commanding Officer, Naval Medical Research Institute, Bethesda, Md.

Dr. W. Ross Adey, Professor, Departments of Anatomy and Physiology and Brain Research Institute, University of California, Los Angeles, Los Angeles, Calif.

Dr. Ralph Smialowicz, Experimental Biology Division, Environmental Protection Agency, Research Triangle Park, N.C.

Dr. Charles Liddle, Experimental Biology Division, Environmental Protection Agency, Research Triangle Park, N.C.

Dr. Andrew T. Huang, Duke University Medical Center, Durham, N.C.

AFTERNOON

Dr. Philip E. Hamrick, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, N.C.

Dr. Richard H. Lovely, University of Washington, Seattle, Wash.

Dr. James W. Frazer, USAF School of Aerospace Medicine, Radiobiology Division, Brooks AFB, Tex.

Dr. William Leach, Bureau of Radiological Health, Division of Biological Effects, Rockville, Md.

Dr. P. Czerski, Institute of Mother and Child, Warsaw, Poland. (Visiting scientist/BRH)

Capt. Kenneth W. Sell, MC, USN, Naval Medical Research Institute, Bethesda, Md.

Dr. W. Wiktor-Jedrzejczak, Military Institute of Post-Graduate Medical Education, Warsaw, Poland. (Visiting scientist/NMRI)

III. GENERAL DISCUSSION AND COMMENTS

Harold Gauper, Jr., Electrical Engineer, Electromagnetic Compatability, Corporate Research and Development, General Electric Company, Schenectady, N.Y.

Dr. William T. Ham, Jr., Professor and Chairman, Department of Biophysics, Medical College of Virginia, Virginia Commonwealth University.

H. Janet Healer, Consultant, Bioscience Programs, Office of Telecommunications Policy, Washington, D.C.

Dr. Samuel Koslov, Special Assistant for Research, Office of Assistant Secretary of Navy, The Pentagon.

William W. Mumford, Engineering Consultant, Morris Plains, N.J.

Dr. Herbert Pollack, Professor Emeritus of Clinical Medicine, George Washington University, Washington, D.C. Medical Consultant.

Dr. Charles Suskind, Professor, College of Engineering, University of California at Berkeley.

Dr. Arthur C. Upton, Professor, Department of Pathology, State University of New York at Stony Brook, Stony Brook, N.Y.

INVITED SPECIALISTS

Dr. Thomas P. Stossel, Chief, Oncology Division, Massachusetts General Hospital, Fruit Street, Boston, Mass.

Capt. Kenneth W. Sell, MC, USN Commanding Officer, Naval Medical Research Institute, Bethesda, Md.

IMMUNOLOGIC STUDIES, A SUMMARY: 6 AGENCIES, 9 RELEVANT PROJECTS

	Relevant projects	Total projects
EPA	2	17
Hew: NIEHS	2	6
BRH	1	19
NIOSH	(1)	2
DOD: Air Force	3	13
Navy	1	43
Total	9	

[1] See Air Force.

Investigator	*Title/frequency*
J. Elder (EPA) and A. Huang (Duke University).	Effect of Exposure of Chinese Hamsters in the Radio and Radar Frequency Range on Chromosome Anomalies in Circulating Lymphocytes (2.45, 9 GHz).
R. Smialowicz, C. Liddle, C. Blackman and (EPA).	Effect of MW Radiation on Immune Defense Mechanisms (2.45, 9 GHz).
D. McRee (NIEHS)	Effects of 2.45 GHz on Embryonic Development and Immunological Response (2.45 GHz).
P. Hamrick (NIEHS)	Effects of 1–10 GHz MW Radiation on Cell Systems (2.45, 5, 10 GHz).
P. Czerski (Poland) W. Leach (BRH)	Effect of MW on the Response of Mice to T Lymphoid Cell Dependennt and Independent Antigens (2.45 GHz).
S. Klainer (Block Engineering)	Effects of RF on Biological Mocromelecules: Mechanisms of Injury (100 MHz).
J. Frazer (AF)	Biological Effects of RF Transmitter Fields (25 kHz–100 GHz).

A. Guy/R. Lovely (University of Washington).	Comparison of RF Field Delivery Techniques and Measurable Results in Culture and Whole Animals (20–500 MHz).
J. Bollinger (Southwest Research Institute).	Biological Effects of VLF Band EMR (25 kHz).
Barnes (University of Colorado)-----	Effects of MW on the Growth Development and Behavior of Biological Systems (2.76 GHz).
W. Wiktor-Jedrzejczak (Poland)-----	MW Stimulation of B Cells in Spleens of Exposed Mice (2.45 GHz).

CHRONIC MICROWAVE IRRADIATION AND ITS EFFECT ON LYMPHOCYTE FUNCTION: A PRELIMINARY STUDY

RALPH SMIALOWICZ, EXPERIMENTAL BIOLOGY DIVISION, HEALTH EFFECTS RESEARCH LABORATORY, ENVIRONMENTAL PROTECTION AGENCY, ENVIRONMENTAL RESEARCH CENTER, RESEARCH TRIANGLE PARK, N.C. 27711

Investigators in the Soviet Union and Eastern European countries have suggested that the immune system of man may be affected by non-ionizing electromagnetic radiation. Changes in the metabolic and functional integrity of lymphocytes obtained from microwave exposed animals have been reported. These findings suggest that the lymphocyte may be a target for microwave radiation. In light of this we have initiated studies to determine if chronic microwave exposure of rats affects lymphocyte function. We have employed a chronic regimen of exposure in an attempt to mimic the type of experiments performed by Soviet and Eastern European investigators.

The in vitro phytoheamagglutinin (PHA)-lymphocyte stimulation test is widely used as an indicator of cell-mediated immune competence. This technique was used to assess the proliferative capacity of blood and lymph node T-lymphocytes obtained from rats chronically exposed to microwave radiation. The incorporation of ^{3}H-thymidine into newly synthesized DNA was used to follow PHA-stimulated lymphocyte blastogenesis.

Time-bred rats were exposed, in a temperature-controlled environment, to either 2450 MHz or 425 MHz microwave radiation. One group of pregnant rats was exposed at an incident power density of 5 mW/cm^2 to 2450 MHz(CW) in an anechoic chamber. Another group was exposed to 425 MHz (CW) in a Crawford cell transmission line at an incident power density of approximately 10 mW/cm^2. The pregnant rats were irradiated for four hours a day seven days a week until parturition. The subsequent offspring were then irradiated, following the same regime, through 40 days of age. At 20 or 40 days of age, rats were sacrificed and lymphocytes from blood and lymph nodes were cultured. Exposure of rats to either frequency resulted in little change in the percentage of lymphocytes or in the number of leukocytes circulating in blood compared to sham irradiated controls. The PHA-response of lymph mode lymphocytes from rats irradiated at 425 MHz was consistently found to be significantly increased over the control response in several experiments. Furthermore, blood lymphocytes in one experiment with animals exposed to 425 MHz microwaves gave an increased PHA-response compared to controls. Changes in the PHA-response of lymph node lymphocytes from rats irridated at 2450 MHz was also observed.

The results of this preliminary study suggest that chronic *in vivo* exposure to microwaves affects the mitogen-stimulated lymphocyte response. The means by which these changes occur and the implications of these changes are not known at this time. Studies are presently in progress to verify these observed changes and to investigate the possible effects of microwaves on the functional integrity of the immune system.

EFFECTS OF MICROWAVES ON ANTIBODY PRODUCTION IN RODENTS

CHARLES G. LIDDLE, EXPERIMENTAL BIOLOGY DIVISION, HEALTH EFFECTS RESEARCH LABORATORY, ENVIRONMENTAL PROTECTION AGENCY, ENVIRONMENTAL RESEARCH CENTER, RESEARCH TRIANGLE PARK, NC 27711

Studies are being conducted to evaluate the circulating antibody (B cell) response of animals exposed to microwaves during the period of antibody response.

Six groups of four mice each were innoculated with Streptococcus pneumonae and irradiated for 2 hours a day with 9 GHz pulsed (1 μsec pulse width, 1 KHz pulse repetition rate) microwaves at an incident average power density of 10 mW/cm^2. Antibody titers and hematological parameters (red blood cell, white blood cell, hemoglobin, hematocrit, differential) were measured on the day following irradiation. The titers in the irradiated animals were significantly higher ($p=.04$) than in the sham irradiated animals, but there were no significant alterations of any of the hematological parameters. Also, three groups of fifteen mice each were irradiated with 2450 MHz CW microwaves at an incident power density of 10 mW/cm^2 in a similar manner. There was no difference in antibody titers between irradiated and sham irradiated animals.

A preliminary study of twenty four rats exposed in utero from day six of gestation until twenty days postnatally (5 mW/cm^2, 4 hours daily) was conducted using 2450 MHz CW microwaves. The antibody titers in the irradiated animals were somewhat higher than in the controls ($p=.10$).

LYMPHOCYTE TRANSFORMATION INDUCED BY MICROWAVE RADIATION

(By A.T. Huang, et al.)

Effects of microwave radiation have been examined in blood lymphocytes from Chinese hamsters irradiated for 15 minutes on 5 consecutive days at 2450 MHz (CW) with power densities from 5 to 45 mW/cm^2. Absorbed dose measurements were determined by twin-well calorimetry. One hour after irradiation, blood lymphocytes were obtained from orbital hemorrhage. Cells were cultured for one day if unstimulated or for three days if stimulated with phytohemagglutinin (PHA) to induce mitosis. After termination, lymphocytes were processed for morphological and cytogenetic analyses with a brief colchicine treatment to arrest cells in metaphase. Microwave radiation caused a transient, reversible and dose-related (5–30mW/cm^2) increase in blastic transformation of unstimulated lymphocytes. However, frequency of cell divisions from PHA-stimulation decreased in irradiated samples. Both effects were evident at 5 mW/cm^2. Autoradiography of cells labeled with [^{3}H]-thymidine showed no evidence of radiation-related DNA repair. Cytogenetic analysis of the irradiated samples demonstrated no significant chromosomal aberration within these power densities.

STUDIES AT NIEHS RELATING TO THE EFFECT OF MICROWAVE RADIATION ON IMMUNITY

Fertile Japanese quail eggs were exposed to continuous wave microwave radiation at an intensity of 5 mW/cm^2 (50 W/m^2) and a frequency of 2450 MHz. The absorbed power density was determined to be 4.03 W/kg. The eggs were exposed throughout the first twelve days of the normal incubation period of 17.5 days. Non-exposed control eggs were incubated in a chamber identical to the exposure chamber. In our first series of experiments, the quail were carefully examined and sacrificed at the time of hatching. Major organ weights (heart, liver, pancreas, adrenals) and blood parameters were compared between exposed and control birds. The only significant differences found were in the hemoglobin concentration (4% increase) and in the monocyte percentage (decrease). The birds appeared normal in all other respects.

In our next series of experiments on the quail, the exposure conditions were as before but after hatching the exposed and control quail were not sacrificed but were reared in the conventional laboratory manner. Weekly body weight measurements were made to compare the growth patterns of exposed and control quail. The weights of the exposed male at the ages of four and five weeks were 12 and 7 percent, respectively, less than the control males. These differences approached statistical significance ($P\leq0.05$). At five weeks of age the quail were challenged with sheep red blood cells (SRBC) and the levels of the anti-SRBC antibodies, determined four days after antigen challenges, were of the same magnitude for both the exposed and control quail. Following this assessment of humoral immunity, the quail were sacrificed and the bursa of Fabricius and spleen were removed and a comparison was made of exposed and control birds. The weights of the bursa of Fabricius and spleen were not altered significantly by the microwave exposure.

In our most recent series of experiments (not completed), the quail were exposed as in the previous two series but were allowed to develop to 22 weeks of age. At this time the birds were sacrificed and organ weights compared and some histological sections taken. Although the studies are not complete, there appears to be some changes in the liver and in the bursa of Fabricius of exposed females that are not observed in control females.

In addition to the above in vivo study relating to immunological function, rat lymphocytes have been exposed in vitro to continuous wave microwave radiation at a frequency of 2450 MHz at intensities of 5 mW/cm^2, 10 mW/cm^2 and 20 mW/cm^2. The corresponding absorbed power densities were determined to be 0.7 mW/gm, 1.4 mW/gm and 2.8 mW/gm. The lymphocytes were exposed for 4 hours, 24 hours or 44 hours either with or without the addition of the mitogen phytohemagglutinin. The transformation of lymphocytes into lymphoblasts was monitored by the addition of tritiated thymidine. No significant differences ($P=.05$) were found in the uptake of tritiated thymidine between exposed and control cultures under the conditions tested.

RESPONSE OF LYMPHOCYTES IN-VITRO TO 30 MHz RADIO FREQUENCY EXPOSURE

Richard H. Lovely, Arthur W. Guy and Thomas J. Sparks, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine, University of Washington School of Medicine, Seattle, Wash.

Freshly obtained primate lymphocytes (M. mulatta) are suspended in culture media and stimulated with PHA mitogen immediately prior to a 20 minute exposure to 30 MHz RF fields. The preparations were exposed to electric field strengths of 5 V/cm with magnetic field strength of 3.77 a/m (within the media) at a controlled temperature of approximately 36.5°C (±0.08 SE) in the exposure system described by Guy [1]. The exposed cultures are then routinely incubated in a 5% CO_2 environment for anywhere from 48 hours up to 96 hours for different cultures obtained from the primate population. Stimulated cells are blocked at metaphase with colcemid and harvested 30 minutes later. Following staining with Giemsa, slides are then examined for the percentage of blast cells present and for the mitotic figures to determine what if any, effects relative to standards, sham-exposed and other culture controls, the RF exposure has had. Expressing either the percentage of blast cells or the mitotic index (percentage cells blocked at metaphase) as difference scores from the appropriate control cultures, we have found no significant differences between RF exposed cells or control cultures in terms of peak mitotic figures or in terms of the distribution in time of the mitotic index. Similarly, we have found no significant differences in the blast cell, data, although these are much more variable. These findings appear to hold both within and across primates tested.

On the other hand, it has taken us nearly a year to collect a rather minimal amount of data. Re-evaluation of our culture outcomes in terms of success rate (obtaining viable cultures from which the appropriate data can be garnered) has revealed that a significantly higher number of lymphocyte cultures fail to grow following 30 MHz RF exposure, viz., when harvested at different points in time there are simply not enough viable cells in the RF exposed group to make the appropriate determinations relative to the various control groups—which do produce viable outcomes.

More recently, we have had a higher success rate in obtaining viable lymphocyte cultures from the RF exposed groups, but preliminary evidence still suggests that the total number of cells available for evaluation is far less than the number available in the control groups, and that this is the case immediately following RF exposure when stimulated first by the PHA mitogen.

Finally, some very preliminary data on the immuno-competence of rats exposed to approximately 1000 hours, 915 MHz microwaves will be presented.

REFERENCE

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LYMPHOCYTIC RESPONSE IN MICE EXPOSED TO 2450 MHz RADIATION

P. Czerski,[1] L. J. Gillespie,[2] W. M. Leach, and T. P. O'Neill, U.S. Department of

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[1] FDA Visiting Scientist, on leave from the National Research Institute of Mother and Child, Department of Genetics, Warsaw, Poland.

[2] Retired.

Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, Division of Biological Effects, Rockville, Maryland 20857

Lymphocytosis of the peripheral blood has been reported in guinea pigs exposed to 2950 MHz radiation (1) and in monkeys exposed to 10.5, 19.27, and 26.6 MHz radiofrequency radiation (2). Lymphoblastoid cell effects in body organs (thymus, spleen, liver, and lmyph nodes) have been reported after exposure of mice to 3.105 MHz radiation (3), and to 2950 MHz radiation (4). Lymphoblastoid transformation of human lymphocytes exposed in vitro to 2950 MHz radiation has also been described (5). A parameter common to most of these cited studies in that multiple repetitive exposures were employed.

The present studies were undertaken to explore the dose-response relationships of the lymphoblastoid response in mice. Adult CF 1 male mice, weighing between 21–35g, were exposed individually to 2450 MHz radiation in an environmentally controlled waveguide apparatus, described elsewhere (6). For one-time exposures 116 mice were used; or three-time exposures, 107 mice were used. Untreated control animals were used with each experiment to establish a normal blood picture; sham-irradiated animals were used as controls for irradiations. At intervals after exposure, blood was taken from the tail vein of mice, and hematological routines were performed, including microhematocrit and total, and differential white blood cell counts on Wright's stained smears.

Results from the studies on mice exposed one time are summarized as follows:

1. Exposure of mice in the range of whole-body absorbed average power (W-B AAP) of 10–35 mW/g resulted in appearance of lymphoblastoid cells, defined as cells which correspond morphologically to lymphoblastoid cells induced in vitro by mitogenic substances, 6–8 days after microwave exposure.
2. At 10 mW/g W-B AAP, a 5 minute microwave exposure resulted in the blastoid response in approximately 50 percent of animals, and a 20 minute exposure resulted in the response in 100 percent of animals. At 20 or 35 mW/g W-B AAP, 100 percent of animals showed the blastoid response.
3. Lymphoblastoid cells may be observed as early as 2 days after microwave exposure, but the data indicated that the response was not consistent.
4. Transient neutropenia and neutrophila was observed during the first 5 days after both microwave and shamp exposure of some animals, particularly after exposures to microwaves in the range 40–95 mW/g W-B AAP.

The results from the studies of mice exposed for 30 minutes at three times to 10 mW/g W-B AAP are summarized as follows:

1. Mice exposed on days 0, 3, and 6 showed lymphoblastoid responses similar to those following a single exposure, in that the first appearance of the lymphoblastoid cell was about 6 days after the last exposure.
2. Mice exposed on days 0, 2, and 5 shows consistently lymphoblastoid cells b6 24 hours after the last exposure, and a peak of the cells about 2–2.5 times higher than that of animals exposed on days 0, 3, and 6.
3. Amplitude nodulation (12 Hz) by a 3310A Hewlett Packard function generator failed to affect the obtained results.

In either of the studies, lymphoblastoid cells were not observed in control or sham-irradiated mice.

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4. Czerski, P.: Microwave Effects on the Blood-Forming System With Particular Reference to the Lymphocyte. Annals New York Acad. Sci. 247, 323, 1974.

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6. Ho, H. S., E. I. Ginns and C. L. Christman: Environmentally Controlled Waveguide Irradiation Facility. IEEE Trans on Microwave Theory and Techniques. Vol. MTT-21, 837, 1973.

Effect of Low Dose Microwaves on the Immune Response of Mice

Capt. K. Sell, MC, USN, Naval Medical Research Institute, Bethesda, Md., Dr. W. Wiktor-Jedrzejczak (Poland), visiting scientist/NMRI

CBA/J male adult mice were exposed to 2450 MHz microwaves (Amplitude modulated 12 Hz) at a forward power 0.6 watts for 30 minutes in an environmentally controlled waveguide facility. The absorbed dose rate was computed from measurements of forward, reflected, and transmitted power and was about 14 mW/g body weight of the animal for each exposure. The experiments were carried out with two groups of mice. One group received a single exposure for 30 minutes, the other group a total of three exposures of 30 minutes each at three day intervals. Sham exposed animals served as controls.

A single exposure to microwaves in such conditions produced a significant increase in the frequency of a subpopulation of B lymphoid cells bearing a receptor for complement (CR+). Triple exposures not only enhanced this effect, but also significantly increased the total frequency of Ig+B cells in spleens of exposed mice. The effect was pronounced seven days after exposure and was independent of cell proliferation since the total number if spleen cells and the incorporation of 3_H-TdR (DNA-precursor), 3_H-Uridine (RNA-precursor) and 3_H-Leucine (protein precursor) by spleen bone marrow, and peripheral blood lymphoid cells of the exposed mice remained unchanged. This effect could not be related to the arrest of further maturation of B cells in CR+ stage, since seven days after a single exposure the number of cells spontaneously forming IgM antibody also increased as evaluated by the plaque assay. Moreover, the functional immune capacity of these mice was evaluated by the response of their spleen cells in vitro to B cell-specific mitogens dextran seulphate lipopolysaccharide, poly I.D., and PPD-tuberculin. While there was no significant increase in their ability to respond to dextran sulphate (which stimulates neonatal B cells), there was a significnt increase in their ability to respond to the other B cell mitogens used.

The proportion of T lymphoid cells (theta-positive) remained unaltered similarly as their functional capacity as evaluated by response of spleen cells in vitro to the T cell specific mitogens-phytohemagglutinin and concanavalin A and to allogeneic stimulator cells in mixed lymphocyte cultures.

Groups of CAB/J male adult mice were injected on day "0" with 0.5 ml of saline or 0.2 ml of T lymphoid cell dependent antigen (i.e. requiring the cooperation of T cells for the production of antibody)—sheep red blood cells (SRBC) or 100 μg of synthetic T cell independent antigen (i.e. B cells produce antibody without cooperation with T cells)—DNP-lysine-Ficoll. On days 1, 2, and 3 the experimental groups consisting of four animals each were exposed to 2450 MHz microwaves. Controls consisted of mice which were sham-exposed. Exposures were performed in an environmentally controlled waveguide facility with a forward power of 0.6 watts to the average absorbed dose rate about 12 mW/g body weight for each exposure. On day 4 mice were sacrificed and their spleen cells were assayed for antibody by the modification of the direct plaque assay of Jerne. Cells from SRBC immunized animals were assayed using SRBC as indicator cells, while cells from DNP-lys-Ficoll immunized mice were plaqued against SRBC coated with appropriate antigen determinant—trinitrobenzene sulfonic acid. Cells from saline injected animals were assayed against both these indicators.

While the number of IgM antibody secreting cells increased in non-immunized (saline) microwave-exposed mice as compared to non-immunized sham animals, the ability to form specific antibody against both T-dependent and T-independent antigen decreased in microwave exposed animals. The difference was, however, statistically significant only in the case of their response to the T-independent antigen.

These results suggest that while microwaves stimulate non-specific reactivity of B lymphoid cells. they simultaneously decrease the number of antigne reactive cells specific for both thymus dependent and independent antigens. These exposure conditions of microwaves in vivo seems to be weakly immunosuppressive. Further studies on the mechanism of this reaction are currently in progress.

SOME EFFECTS OF ELECTROMAGNETIC RADIATION ON THE IMMUNE SYSTEM

(James W. Frazer, Ph. D., USAF School of Aerospace Medicine,
Radiation Sciences Division, Brooks AFB, Tex.)

Relatively high values of specific absorbed radiation (SAR) have been found in the extremities of animals exposed to frequencies below their geometric resonance frequency with field electric vectors paralleling the extremity. In other instances, the close apposition of the base of the brain to the dielectric discontinuity offered by the floor of the cranium insures higher than average SAR in this region also. Both of these circumstances predict some effect on the maturation and liberation of bone marrow elements, as well as effects on release of pituitary hormones with secondary effects on the reticulo endothelial system.

Frequencies utilized in the series of experiments reported range from 25 kHz to 26 MHz. Fields employed were sufficient to produce appreciable in-tissue fields, but insufficient to produce measurable hyperthermia except at 26 MHz.

In fields of 25 kHz, 15 kV/meter, it was found that tritiated thymidine incorporation into DNA of animals exposed for 1 hour a day continuously increased over a period of approximately three months. Littermate controls showed no such increases. A survey for parasite infestation revealed no qualitative difference between the groups of animals, though both groups were extensively infested with round worms present at the time of arrival. Cells tested were removed from marrow and cultured so that most cells were marrow lymphocytes.

In another series of experiments, it was found that lymphocytes removed from monkeys (Macaca mulatta) 3 days following a single exposure to fields of 10, 19, or 26 MHz fields, 5880 V/m, 17 percent duty cycle responded to addition of phytohemaglutinin 3–5x as much as pair handled controls. Culture of cells extended 96 hours after removal from the animal. Lymphocytes were cultured in the presence of RBC. Hyperthermia, measured by rectal temperature and by radiometer surface scan, was only produced at 26 MHz.

Rats exposed daily to 19 MHz fields in the near-field synthesizer with electric and magnetic vectors coincident at 8 kV/m and 50 Amp/m had a depressed lymphocyte count when sampled on the 4th day of radiation, and demonstrated a small increase in plasma alpha 2 globulin content. No significant changes were found in plasma cortisol, serum aldosterone, or 24 hour excretions of 17 hydroxy or 17 ketosteroids or aldosterone. Animals brought to the same rectal temperature by exposure for a similar period of time to a warm environment demonstrated an increased aldosterone excretion as expected.

Rats given a single acute exposure to 19 MHz, 3400 V/m fields responded with a decrease in circulating lymphocytes reaching minimum 7-12 hours post exposure and returning nearly to normal in 24 hours. Another group exposed to 1700 V/m showed no such response.

A large series of molecules was exposed in solution to frequencies ranging from 10 MHz to 100 MHz. Evidence of alteration in molecular structure was obtained from Raman or Fourier transform infrared spectrometry. Molecular species ranged from glycine, through several nucleotides, t-RNA, chymotrypsin to calf thymus DNA. Lower molecular weight compounds did not demonstrate alterations in structure under the carefully thermostatted conditions used. E. coli t-RNA gave evidence of hydrogen bond disruption and increased P–O stretching amplitudes. Chymotrypsin behaved as if there was a "Stiffening" of the peptide chain. DNA showed little evidence of perturbation, other than equivocable evidence of change in hydration.

We believe the data indicate, though do not prove, the existence of 2 effects of the application of the fields utilized. One is a response similar to that expected from hyperthermia; i.e., a transient glucocorticoid release and lymph depression with a time course similar to that shown to occur in higher frequency fields by Michaelson, and whose consequences to lymphocytes was demonstrated many years ago as part of the "Alarm" reaction.

The other effect is more subtle, depending on direct interaction with a set of macromolecules either in the releasing sequences, or in the lymphocyte itself. This effect is expected to occur at low fields, and should be investigated in pulsed fields.

ADVANCE PROGRAM AND
GENERAL INFORMATION

1977 INTERNATIONAL SYMPOSIUM on the BIOLOGICAL EFFECTS OF ELECTROMAGNETIC WAVES

Sponsored by
The INTERNATIONAL UNION OF RADIO SCIENCE,
and
The U.S. NATIONAL COMMITTEE FOR URSI
With the Cooperation of
The INTERNATIONAL RADIATION PROTECTION ASSOCIATION

October 30-November 4, 1977
ARLIE, VIRGINIA, U.S.A.

1977 INTERNATIONAL SYMPOSIUM STEERING COMMITTEE

Chairman:
Saul W. Rosenthal
Polytechnic Institute of New York
Route 110
Farmingdale, NY 11735, USA

Symposium Committee Chairman:
Moris L. Shore
Bureau of Radiological Health
5600 Fishers Lane
Rockville, MD 20852, USA

Technical Program Chairman:
A. W. Guy
Department of Rehabilitation Medicine (RJ-30)
University of Washington
Seattle, WA 98195, USA

Finance Chairman:
Thomas C. Rozzell
Office of Naval Research
800 Quincy St.
Arlington, VA 22217, USA

Symposium Address:
Finance Chairman
URSI BioSymposium
P.O. Box 353
Merrifield, VA 22116, USA

Publicity Chairman:
Paul E. Tyler
Naval Medical R & D Command
National Naval Medical Center
Bethesda, MD 20014, USA

On-Site Arrangements Chairman:
Edward L. Hunt
Division of Neuropsychiatry
Walter Reed Army Institute of Research
Washington, DC 20012

Editors, Sympos. Publications:
Don R. Justesen
U.S. Veterans Administration Hospital
4801 Linwood Blvd.
Kansas City, MO 64128, USA

Ramon C. Baird
Electromagnetics Division
National Bureau of Standards
Boulder, CO 80302, USA

1977 INTERNATIONAL SYMPOSIUM

On The

BIOLOGICAL EFFECTS OF ELECTROMAGNETIC WAVES

GENERAL

From October 30 through November 4, 1977, the URSI, Commissions A and B, and the USNC/URSI, Commissions A and B, with the cooperation of the IRPA, will conduct the INTERNATIONAL SYMPOSIUM on the BIOLOGICAL EFFECTS OF ELECTROMAGNETIC WAVES at Airlie, Virginia, U.S.A. The URSI General Assembly of 1975, held in Lima, Peru, adopted a Resolution which indicated a growing concern with biological effects of electromagnetic radiation and the need for the cooperation of physical scientists with biomedical scientists and organizations to address this interdisciplinary topic. This first INTERNATIONAL SYMPOSIUM on the BIOLOGICAL EFFECTS OF ELECTROMAGNETIC WAVES is the direct result of the activities of the URSI Working Group in support of the Resolution and of the activities of the U.S. Commissions A and B of the USNC/URSI to foster interdisciplinary exchanges of information and viewpoints on an international scale.

LOCATION

The 1977 INTERNATIONAL SYMPOSIUM on the BIOLOGICAL EFFECTS OF ELECTROMAGNETIC WAVES will be held in the self-contained conference facilities of the Airlie House, Airlie, Virginia, U.S.A., located in a lovely country setting of the foothills of the Blue Ridge Mountains. Although only a few miles and minutes removed from national and international air terminals and the busy urban scene of the national capital city, Washington, DC, these facilities provide the protective isolation for SYMPOSIUM participants to meet together formally and informally with maximum ease and minimal distraction. A description brochure of the Airlie House conference facilities accompanies this announcement.

The SYMPOSIUM will have exclusive use of the Airlie House conference facilities during the week of the meetings. The main building, Airlie House, will be used for registration, all technical meetings and dining (three meals daily, including the Banquet). Lodging for the first 190 registered participants will be provided in nearby residence at Airlie (Silo House, Farmer's House, Carriage House, Groom's Cottage and Lake Cottage). Lodging for additional registered participants will be arranged in nearby motels (Warrenton, VA) with transportation provided to and from the SYMPOSIUM and all meals taken at Airlie House.

Because the Airlie facilities will be so fully occupied by the SYMPOSIUM, the Committee will not make lodging and dining arrangements for non-participants. Participants that plan to be accompanied by family members must make their own arrangements for lodging and meals. A listing of nearby motels is provided, without any endorsement by the SYMPOSIUM, solely to accommodate those that register for the SYMPOSIUM but wish to make their own arrangements for lodging.

The Airlie facilities include a large number of small sized conference and meeting rooms in Airlie House and the resident houses. These can be made available during the week for use by small groups of participants when technical meetings of the SYMPOSIUM are not in session. Prior arrangements for such use can be made by contacting the ON-SITE ARRANGEMENTS CHAIRMAN or, during the SYMPOSIUM, by contacting the SYMPOSIUM OFFICE, Foxes Den, Airlie House.

A Publicity-Press Room will be maintained in Airlie House during the period of the SYMPOSIUM.

ADVANCE REGISTRATION

The advance registration fee is $80. The Advance Registration form and the Application for Lodging form accompany this announcement. The completed forms and the registration fee must be received on or before Monday, September 19, 1977, for United States, Canadian and Mexican residents, and Monday, October 3, 1977, for overseas residents. The registration fee after September 19 (domestic) and after October 3 (overseas) is $100.

The Advance Registration form, the registration fee and the Application for Lodging form should be mailed to the FINANCE CHAIRMAN in the envelope provided.

Those registering in advance by mail may pick up their registration materials (badge, program notices, etc.) at the Advance Registration Desk at Airlie House (Board Room) at time of arrival.

Advance registration for less than the full period of the SYMPOSIUM will not be honored. Only those cancellations received on or before October 3, 1977, will be honored.

ON-SITE REGISTRATION

Advance registration by mail is strongly recommended. The registration fee at the SYMPOSIUM will be $100 and registration for any one day of the SYMPOSIUM is $30. The Registration Desk at Airlie House (Board Room) will be open from 1400-2000 hours, Sunday, October 30, 1977, and will be open after 0730 hours on subsequent days.

Attendance at all technical sessions, meals and other uses of the Airlie House conference facilities during the SYMPOSIUM will require registration. Access to conference rooms and dining under the SYMPOSIUM arrangements will require that the registration badge be shown each time.

The SYMPOSIUM will make an effort to arrange lodging for those registering on-site for the period of the SYMPOSIUM. This will be on a first-arrival basis starting at 1400, Sunday, October 30, 1977. Again, it is urged that lodging be arranged well in advance of arrival since lodging capacity at Airlie House and in Warrenton is limited.

One-day registrants will have to make their own arrangements for lodging. Meals will be provided on a space-available basis at the "day guest" rates charged at Airlie House (breakfast, $5.75; luncheon, $8.50; dinner, $10.25; Banquet, $12.75, plus 4% state sales tax).

PUBLICATIONS

Each participant registered for the SYMPOSIUM will receive one copy of the 1977 INTERNATIONAL SYMPOSIUM PROGRAM and ABSTRACTS at registration. Extra copies of this publication can be obtained at the SYMPOSIUM for $5.00 at the registration desk, Board Room, Airlie House. After the SYMPOSIUM, copies of the PROGRAM and ABSTRACTS can be obtained from Mr. Richard Y. Dow, USNC/USRI, National Academy of Sciences, 2101 Constitution Avenue NW, Washington, DC 20418.

Each participant registered for the SYMPOSIUM will also receive one copy of a volume of refereed papers from the 1977 INTERNATIONAL SYMPOSIUM that will be published as a special supplement to *RADIO SCIENCE* in 1978. Professor D. R. Justesen and Dr. R. C. Baird will serve as the co-editors of this volume. Extra copies of this volume can be ordered at the SYMPOSIUM at the pre-publication rate of $13.50 at the registration desk, Board Room, Airlie House. After publication, the cost of the volume will be substantially higher.

Participants that are registered for less than the full period of the SYMPOSIUM will *not* receive a copy of the 1977 INTERNATIONAL SYMPOSIUM special supplement to *RADIO SCIENCE* as part of the registration fee but can place an order for this volume at the pre-publication rate of $13.50 at the registration desk, Board Room, Airlie House.

SYMPOSIUM INFORMATION

Prior to October 29, general questions concerning the conference may be directed to the SYMPOSIUM COMMITTEE CHAIRMAN, Dr. Moris L. Shore. Questions concerning program should be directed to the TECHNICAL PROGRAM CHAIRMAN, Dr. A. W. Guy; those concerning registration to the FINANCE CHAIRMAN, Dr. Th. C. Rozzell; those concerning publicity to the PUBLICITY CHAIRMAN, Dr. P. E. Tyler; and those concerning conference facilities, lodging, meals and transportation to the ON-SITE ARRANGEMENTS CHAIRMAN, Mr. E. L. Hunt. The addresses are listed elsewhere in this announcement.

During the period of the SYMPOSIUM, the Registration and Information Office, located in the Board Room, Airlie House, will be open from 1400-2000 hours, Sunday, October 30, and from 0730-1800 hours on subsequent days, closing at 1400 hours, Friday, November 4. Telephone messages for participants will be accepted at (703) 347-1300 (or 273-6554 from Washington, D.C. area) during these hours. A message board and a lodging directory will be located in the Board Room, available during the hours that Airlie House is open (0700-2300 hours).

AUDIO-VISUAL EQUIPMENT

Projection equipment available for the technical sessions (Federal Room, Airlie House) will be 35 mm and viewgraph (overhead) projectors. Persons needing other types of equipment should make special arrangements well in advance of the meeting with the On-Site Arrangements Chairman. *Note*: Visual aid materials should be prepared with clarity and visibility in mind. Use oversize lettering and heavy lines. Be sure to number and identify all visual aid materials.

TECHNICAL PROGRAM

Times listed in the program for technical papers will be followed. Because of the arrangements made for serving meals, closely scheduled with the meetings, adjournment of sessions just prior to Luncheons and Dinners will be rigidly followed.

Each technical session will be co-chaired, with one of the chairmen being an overseas participant of the Symposium. The co-chairmen for each session will be announced in the PROGRAM AND ABSTRACTS booklet.

There will be no concurrent sessions. The main meeting room (Federal Room) will be augmented by a satellite meeting room (East Room). The second meeting room will be outfitted with video monitors, audio speakers and a microphone to provide means for full participation.

ROUND TABLE SESSION

In addition to the full schedule of technical sessions, a special round table on a current research topic of wide, general interest will be convened on Tuesday evening, November 1. Topic and speakers are listed at the end of the Technical Program.

SYMPOSIUM BANQUET

A reception and Banquet will be held at Airlie House for SYMPOSIUM participants on Wednesday evening, November 2, with Banquet service to start at 1900. There will be no additional charge to participants for the Banquet. The program and speaker will be announced.

TRANSPORTATION TO AIRLIE, VIRGINIA

A map of highway routes from Washington, D.C. and from Dulles and National airports, to Airlie, VA, is contained in the descriptive brochure of Airlie House that accompanies this announcement. Travel time from Washington, D.C. by automobile is approximately one hour.

Scheduled Trailways buses operate from Washington, D.C. to Warrenton, VA several times throughout the day, with a one-way charge of slightly more than $3.00. Information on transportation to Airlie from Warrenton may be obtained by contacting the SYMPOSIUM by telephone (347-1300).

Transportation from Dulles International Airport or from National Airport can be obtained by taxi and limosine services. The limosines are operated by Greyhound Airport Service from a dispatcher desk located centrally at Dulles and in the main terminal at National. From Dulles Airport the price for transportation arranged by the SYMPOSIUM on Sunday afternoon and evening, October 30, will be $5.50 each, cash, and from National Airport, $7.50 each. To help coordinate transportation from both airports to Airlie, a SYMPOSIUM official will be located at the dispatcher desk at each airport. Participants wishing to take advantage of this coordination are to inform the SYMPOSIUM, using the postal card form accompanying this announcement titled "Arrival Information for Sunday, 30 October." This should be mailed for receipt by October 24 to the ON-SITE ARRANGEMENTS CHAIRMAN. Those traveling from Washington, D.C. and vicinity can take advantage of this service by using the postal card mailer to inform the SYMPOSIUM of the time on October 30 that they plan to get to an airport by surface transportation. Coordination of Greyhound airport limosine service to Airlie will be provided by the SYMPOSIUM only as indicated, on October 30. Travel from Airlie to the airports at the end of SYMPOSIUM will be arranged for Friday, November 4, and participants should watch for an announcement or inquire at the Registration and Information desk, Board Room, Airlie House, on Thursday, November 3.

LODGING, MEALS AND LOCAL TRANSPORTATION

The arrangement for lodging and meals for the SYMPOSIUM is by the American Plan and, because of the limited capacity, will be made available for only the first 350 registrants. The rate for the SYMPOSIUM participants is $27.50 per day ($137.50 for the 5 days) plus a 4% state sales tax. Payment to Airlie House in cash or by check (no credit cards) is due on departure on Friday, November 4. Adjustments will be made for late arrivals to 1000 hours, Monday, October 31, for missing, in progression, Sunday evening dinner, one night's lodging and breakfast on Monday, and for early departures Friday morning, November 4, missing Friday lunch. No adjustments will be made for meals made available but not taken during the rest of the SYMPOSIUM period.

Registered participants who make their own arrangements for lodging during the SYMPOSIUM will be offered meal service at the SYMPOSIUM rates if pre-paid at the time of registration. This rate is $17.00 per day ($85.00 for the 5 days) plus a 4% state sales tax and with adjustments available for the first two meals and the last meal that might not be taken during the period of the SYMPOSIUM.

Participants who register for less than the full period of the SYMPOSIUM or who do not wish to take advantage of the prepayment for meals at the SYMPOSIUM rate will be charged at the "Day Guest" rate for each meal taken. These rates are: breakfast—$5.75, lunch—$8.50 and dinner—$10.25, plus 4% state sales tax. Meals for such participants will be provided on a space-available basis.

Double occupancy lodging is standard for the Airlie facilities. At an additional charge of $7.00 per day, plus a 4% state sales tax, a limited number of single occupancy rooms will be available in motel facilities reserved in Warrenton for the SYMPOSIUM. Assignment of each participant's roommate will be made by the SYMPOSIUM in making room assignments except where both participants prearrange the assignment. Each must indicate this preference for the other registrant at the time of registration or on the "Application for Symposium Lodging" form submitted with the "Advanced Registration" form. Both forms and an addressed envelope ready for postage and mailing accompanies this announcement. If the applicant has no preference for a roommate assignment, the appropriate blank on the application should state "no preference" or be left blank. Room assignments will be made on a first-received (advance registration) or first-arrive (on-site registration) basis. Residence space at Airlie will be assigned first, with applicants after the first 190 assigned to motel spaces reserved for the SYMPOSIUM in Warrenton.

SYMPOSIUM participants who are lodged in Warrenton motels by arrangements with Airlie House will be provided free limosine service to and from their motels, scheduled to deliver participants at Airlie House in time for breakfast and to return late evening. This transportation will also be available during the day according to need (consult Information Desk, Board Room). Free parking is available for participants who employ their own vehicles for transportation.

MEAL SCHEDULES

Only the eating facilities at Airlie House are available locally for the SYMPOSIUM (Commercial restaurants on RT 211 are three miles, or more, in distance from Airlie House). Meal times are scheduled as follows:

Breakfast (all mornings): 0715-0830

Luncheons; Monday-Thursday: 1230-1330
Friday: 1245-1345

Dinners; Sunday: 1900-2030
Monday, Tuesday and Thursday: 1830-2000
Wednesday:(Banquet): 1900-2100

All meals, except the Banquet, are served buffet style. A Coffee/Tea Break (no cost) is scheduled mid-morning and mid-afternoon during each day of the SYMPOSIUM. A bar will operate at Airlie House (Studio Room) after adjournment of each day's technical sessions through the dinner period and two additional bars (Silo House Tavern and Lodge Bar) will operate through the dinner and evening periods. A standard charge will be made for drinks and set ups.

ANTICIPATED WEATHER CONDITIONS

Early November at Airlie, VA, is a transitional season of the year. It usually is sunny and warm during the day (75 °F) and very cool during evening and night times, requiring sweaters or light covering. Rain, or even light snow flurries can occur at this time of year and participants, accordingly, should come prepared for such a contingency.

LOCAL MOTELS

This listing of motels, all located 3 miles or more from Airlie, VA, is provided (without any endorsement by the SYMPOSIUM) for information to participants registered for the SYMPOSIUM who need to make their own arrangements for lodging. These motels are listed alphabetically and the number of single and double rooms each has for rent is indicated.

Name and Address	*Number of Rooms*
Cavalier Motel Warrenton, VA (703) 347-4333	10 single, 20 double
Holiday Inn Manassas, VA (703) 361-0131	9 single, 120 double
Howard Johnson Warrenton, VA (703) 347-4141	28 single, 28 double
Jefferson Motel Warrenton, VA (703) 347-4000	10 single, 18 double
Lee-Hi Motel Gainesville, VA (703) 347-3414	3 single, 8 double
Ramada Inn Manassas, VA (703) 361-0221 (or -1424)	123 double
Rip Van Winkle Motel Warrenton, VA (703) 347-7272	23 double
Terrace Motel Gainesville, VA (703) 347-2427	14 single, 4 double
Warrenton Motor Lodge Warrenton, VA (703) 347-2600	22 double

TECHNICAL PROGRAM

MONDAY MORNING, OCT. 31, 0830-1000

OPENING SESSION

Chairman: Don R. Justesen, Veterans
Administration Hospital, Kansas City, MO 64128

Symposium Welcoming and Special Announcements

Physical-Science Keynote Address
Interdisciplinary and International Contributions to Electromagnetic Bioeffects Research: Past Performance and Challenges for the Future. Professor Curtis C. Johnson, Chairman, Department of Bioengineering, University of Utah, Salt Lake City, UT 84112.

Biological-Science Keynote Address
Some Perspectives on the Biological Response to Non-Ionizing Electromagnetic Radiation. Dr. Joseph C. Sharp, Deputy Director, Life Science Division, NASA-AMES, Moffett Field, CA 94305.

1000-1025 Coffee/Tea Break

MONDAY MORNING, OCT. 31, 1025-1225

INSTRUMENTATION

Session A

A-1 1025 **An Investigation of Thermistors for Temperature Mapping of Biological Specimens during EM Radiation:** J. Toler, E. Burdette, J. Seals, and F. Cain, Georgia Institute of Technology, Atlanta, GA 30332

A-2 1035 **A Fiber-Optic Probe with Semiconductor Sensor for Temperature Measurements in Electromagnetic Fields:** Douglas A. Christensen, Department of Bioengineering, University of Utah, Salt Lake City, UT 84112

A-3 1045 **Inexpensive Nonmetallic Differential Temperature Probe for Microwave Dosimetry:** Richard G. Olsen and Efrain A. Molina, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508

A-4 1055 **Viscometric Thermometer: An Instrument for Temperature Measurement in EM Fields:** Michael M. Chen, Charles A. Cain, Jeffrey Mullin and Katherine Loh, Department of Bioengineering, University of Illinois at Urbana-Champaign, Urbana, IL 61801

A-5 1105 **Response of Insulated Electric-Field Probes in Models of Finite Heterogeneous Biological Bodies:** H. Mousavinezhad, K. M. Chen, and D. P. Nyquist, Department of Electrical Engineering and Systems Science, Michigan State University, East Lansing, MI 48824

A-6 1115 **Carbon Electrodes for EEG Measurements in Microwave Research: C. K. Chou and A. W. Guy, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195**

A-7 1125 **Analysis of the Accuracy of Electromagnetic-Components Measurement in the Near Field:** Tadeusz M. Babij and Hubert Trzaska, Technical University of Wrocław, Wroclaw, Poland

A-8 1135 **Variability in Measurements of Power Density:** G. J. Hagan, G. L. Donovan, and R. L. Carpenter, Bureau of Radiological Health, Division of Biological Effects, Winchester Engineering and Analytical Center, Winchester, MA 01890

1145-1225 **Discussion**

1230-1330 Luncheon

MONDAY AFTERNOON, OCT. 31, 1330-1500

EXPOSURE SYSTEMS

Session B

B-1 1330 **Miniature Anechoic Chamber for Chronic Exposure of Rodents to Plane-Wave Microwave Fields:** Arthur W. Guy, Bioelectromagnetics Research Laboratory Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

B-2 1340 **Circularly Polarized 2450-MHz Waveguide System for Chronic Exposure of Rodents:** Arthur W. Guy and Jack Wallace, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

B-3 1350 **Improving Far-Field Uniformity in Nonideal Microwave Anechoic Chambers by Adding Absorptive Collar to Feedhorn:** Richard G. Olsen and W. G. Lotz, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508

B-4 1400 **Long-Term Microwave Exposure of Marine Animals:** Donald I. McRee, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709 and Howard Wachtel, Duke University, Durham, NC 27706

B-5 1410 **A System for the Exposure of Large Numbers of Small Laboratory Animals to 60-Hz Electric Fields:** W. T. Kaune, J. R. Decker, R. D. Phillips and D. L. Hjeresen, Battelle Pacific Northwest Laboratories, Richland, WA 99352

B-6 1420 **A System for Continuous Exposure of Miniature Swine to 60-Hz Electric Fields: M. F. Gillis, C. H. Allen, J. L. Beamer, T. W. Jeffs, J. R. Decker and R. D. Phillips, Battelle Pacific Northwest Laboratories, Richland WA 99352**

1430-1500 **Discussion**

1500-1525 Coffee/Tea Break

MONDAY AFTERNOON, OCT. 31, 1525-1610

BIOEFFECTS OF MILLIMETER WAVE RADIATION

Session C

C-1 1525 Possible Detection in vivo of Latent Viruses in Tumor and Bacterial Cells and Their Induction by Millimeter Microwaves; Sydney J. Webb, Department of Physics, University of South Florida, Tampa, FL 33620

C-2 1535 Microwave Effects in Drosophila melanogaster: M. Dardalhon, Fondation Curie-Institut de Radium, Section de Biologie, 26, rue d'Ulm, 75231 Paris Cedex 05, France, A. J. Berteaud and D. Averbeck, Groupe de Recherche "Organisation Moléclair et Macromoléculaire" du C.N.R.S., 2, rue Henry Dunant, 94320 Thiais, France

C-3 1545 Effects of Millimeter Waves on Living Tissue: O. P. Gandhi, D. W. Hill, L. M. Partlow, C. C. Johnson, and L. J. Stensaas, University of Utah, Salt Lake City, UT 84112

1555-1610 **Discussion**

MONDAY AFTERNOON, OCT. 31, 1610-1710

PHYSIOLOGICAL EFFECTS I

Session D

D-1 1610 Electromagnetic Waves Affect the Wingbeats of the Housefly: Sheldon S. Dandler and Andrew Voyatzakis, Bioelectromagnetics Laboratory, Department of Electrical Engineering, Northeastern University, Boston, MA 02115

D-2 1620 Absence of ECG and Respiratory Changes in Turtles and Tortoises Exposed to Microwave Fields of Low Density: W. F. Flanigan, Jr., W. R. Lowell, and R. L. Seeley, Naval Ocean Systems Center, San Diego, CA 92152

D-3 1630 Heart-rate Modification in vivo from Irradiation by Electromagnetic Energy: Edwin S. Eichert, III and Allan H. Frey, Randomline, Inc., Huntingdon Valley, PA 19006

D-4 1640 Interaction of the Neuron with Alternating Current Fields: Jan Musil, Institute of Hygiene and Epidemiology, Srobarova 48, 100 42 Prague 10, Czechoslovakia

1650-1710 **Discussion**

TUESDAY MORNING, NOV. 1, 0830-1000

PHYSIOLOGICAL EFFECTS II

Session E

E-1 0830 The Effect of Electromagnetic Energy on Spontaneous Contractions of Smooth Muscle: Ernest R. Whitcomb and Claude M. Weil, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

E-2 0840 Effects of Microwave Radiation on the Rat's Pituitary-Thyroid Axis: Shin-Tsu Lu, Nancy Lebda, and Sol M. Michaelson, The University of Rochester, School of Medicine and Dentistry, Rochester, NY 14642

E-3 0850 Effects of Hypophysectomy and Dexamethasone on the Rat's Adrenal Response to Microwave Irradiation: W. Gregory Lotz, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508, and Sol M. Michaelson, The University of Rochester, Rochester, NY 14642

E-4 0900 Growth Hormone Levels of Rats Exposed to 2450-MHz (CW) Microwaves: W. Gregory Lotz, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508, Sol M. Michaelson and Nancy J. Lebda, the University of Rochester, Rochester, NY 14642

E-5 0910 Effects of Handling and Surgical Treatment on Convulsive Latencies and Mortality of Tumor-Bearing Rats to 2450-MHz Microwave Radiation: Don R. Justesen, Robert A. Morantz, Martina Clark, Dennis Reeves, and Michelle Mathews, Neuropsychology and Neurosurgery Research Laboratories, Veterans Administration Hospital, Kansas City, MO 64128

E-6 0920 Cataractogenic Response of Rabbits to Pulsed Microwaves of High-Peak Low-Average Power: E. S. Ferri and M. E. G. Foti, Bureau of Radiological Health, Division of Biological Effects, Winchester Engineering and Analytical Center, Winchester, MA 01890

0930-1000 **Discussion**

1000-1025 Coffee/Tea Break

TUESDAY MORNING, NOV. 1, 1025-1225

THEORETICAL DOSIMETRY—I

Session F

F-1 1025 Radiofrequency Radiation Dosimetry Handbook: Description of the Second Edition: C. H. Durney, C. C. Johnson, P. W. Barber, H. Massoudi, M. Iskander, Departments of Bioengineering and Electrical Engineering, University of Utah, Salt Lake City, UT 84112, S. J. Allen and J. C. Mitchell, USAF School of Aerospace Medicine, Aerospace Medical Division, Brooks AFB, TX 78235

F-2 1035 A Technique for Calculating Absorption of Radio-Frequency Energy in Models of Man at and above the Resonant Frequency: M. F. Iskander, C. H. Durney, P. W. Barber, and H. Massoudi, Departments of Electrical Engineering and Bioengineering, The University of Utah, Salt Lake City, UT 84112

F-3 1045 Absorption Characteristics of a Prolate Spheroidal Model of Man at and near Resonant Frequencies: H. Lee and V. K. Tripathi, Electrical and Computer Engineering Department, Oregon State University, Corvallis, OR 97331

F-4 1055 **Indexing Absorption of Electromagnetic Energy by Biological Objects with Prolate Spheroidal Models:** James C. Lin and Chuan-Lin Wu, Department of Electrical and Computer Engineering, Wayne State University, Detroit, MI 48202

F-5 1105 **Application of Impedance-Boundary Conditions in Problems of Microwave Dosimetry:** Leonard S. Taylor and Tuan H. Dao, Electrical Engineering Department, University of Maryland, College Park, MD 20742

F-6 1115 **Geometrical-Optics and Exact Solutions for Internal Fields and SARs in a Cylindrical Model of Man as Irradiated by an Electromagnetic Plane Wave:** Habib Massoudi, Carl H. Durney, and Curtis C. Johnson, Departments of Electrical Engineering and Bioengineering, University of Utah, Salt Lake City, UT 84112

F-7 1125 **RF-Energy Absorption by Biological Models: Calculations Based on Geometrical Optics:** G. Ian Rowlandson and Peter W. Barber, Department of Bioengineering, University of Utah, Salt Lake City, UT 84112

F-8 1135 **Some Recent Results on Deposition of Electromagnetic Energy in Animals and in Models of Man:** O. P. Gandhi and M. J. Hagmann, Departments of Electrical Engineering and Bioengineering, University of Utah, Salt Lake City, UT 84112

1145-
1225 **Discussion**

1230-1330 Luncheon

TUESDAY AFTERNOON, NOV. 1, 1330-1430

DOSIMETRY-THEORETICAL STUDIES—II
Session G

G-1 1330 **A Computer Model of Temperature Distribution Inside Lossy Spheres after Microwave Radiation:** W. S. Janna, E. P. Russo, University of New Orleans, LA 70146, and R. McAfee, V.A. Hospital, New Orleans, LA 70146

G-2 1340 **Numerical Calculation of Electromagnetic Energy Deposition in a Realistic Model of Man:** M. J. Hagmann, O. P. Gandhi, and C. H. Durney, Departments of Electrical Engineering and Bioengineering, University of Utah, Salt Lake City, UT 84112

G-3 1350 **Numerical Calculation of Electromagnetic Energy Deposition in Models of Man with Grounding- and Reflector-Effects:** M. J. Hagmann, O. P. Gandhi, and C. H. Durney, Departments of Electrical Engineering and Bioengineering, University of Utah, Salt Lake City, UT 84112

G-4 1400 **Induced EM Fields in Human Bodies and Heads:** Kun-Mu Chen, H. Mousavinezad, Sutus Rukspollmuang, and D. P. Nyquist, Department of Electrical Engineering and Systems Science, Michigan State University, East Lansing, MI 48824

1410-
1430 **Discussion**

TUESDAY AFTERNOON, NOV. 1, 1430-1545

DOSIMETRY—EXPERIEMENTAL STUDIES
Session H

H-1 1430 **Far-Field Microwave Dosimetric Measurements in a Man-Size Phantom:** Richard G. Olsen, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508

H-2 1440 **Development and Use of a Calorimeter to Measure Specific Absorption Rates in Small Laboratory Animals:** Stewart J. Allen and William D. Hurt, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

H-3 1450 **Absorption of Electromagnetic Energy by Phantom Muscle-Spheres and by Birds of Differing Size:** C. K. Chou and A. W. Guy, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

H-4 1500 **The Number and Spacing of Animals Simultaneously Exposed to Microwaves in a Free Field Affect the Dose Rate:** James B. Kinn, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

H-5 1510 **Pulmonary Diagnostics with Non-Invasive Microwave Methods:** M. F. Iskander, C. H. Durney, D. J. Shoff, Departments of Electrical Engineering and Bioengineering, and D. G. Bragg, Department of Radiology, University of Utah, Salt Lake City, UT 84112

1520
1545- **Discussion**

1545-1610 Coffee/Tea Break

TUESDAY AFTERNOON, NOV. 1, 1610-1740

DEVELOPMENTAL EFFECTS
Session I

I-1 1610 **Developmental Effects of Microwaves in Tenebrio molitor: Experiments to Detect Possible Influences of Radiation Frequency and of Culturing Protocols:** William F. Pickard and Richard G. Olsen, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508

I-2 1620 **The Effect of Microwave Power Level on Teratogenesis in Tenebrio molitor:** D. R. Green, Jr., F. J. Rosenbaum, and W. F. Pickard, Department of Electrical Engineering, Washington University, St. Louis, MO 63130

I-3 1630 **The Influence of Microwaves on Development of the Rat:** Sol M. Michaelson, Ronnie Guillet, and Franklin W. Heggeness, The University of Rochester, School of Medicine and Dentistry, Rochester, NY 14642

I-4 1640 **Repeated Exposure to Microwaves and Environmental Temperature Affect Body Growth of Neonatal Rats:** Shin-Tsu Lu, Susanne Pettit and Sol M. Michaelson, Department of Radiation Biology and Biophysics, School of Medicine and Dentistry, The University of Rochester, Rochester, NY 14642

I-5 1650 **Effects of Pre- and Post-Natal Exposures to 918-MHz Microwave Radiation on Development and Behavior in Rats:** R. B. Johnson, S. Mizumori, D. E. Myers, A. W. Guy, and R. H. Lovely, Bioelectromagnetics Research Laboratory, Departments of Rehabilitation Medicine and Psychology, University of Washington, Seattle, WA 98195

I-6 1700 **Embryotrophic Effects of Pulsed Electrostatic Fields:** Hana Pafková, Institute of Hygiene and Epidemiology, Srobarova 48, 100 42 Prague 10, Czechoslovakia

1710
1740- **Discussion**

TUESDAY EVENING, NOV. 1, 2000-2200

ROUND TABLE ON BLOOD-BRAIN-BARRIER PERMEABILITY EFFECTS

Session RT

Chairman: D. R. Justesen, Veterans Administration Hospital, Kansas City, MO 64128

RT-1 **Studies of Blood-Brain-Barrier Permeability after Microwave Radiation:** James H. Merritt, USAF School of Aviation Medicine, Brooks AFB, TX 78235

RT-2 **Effects of Microwave-Induced Hyperthermia on the Rat Blood-Brain Barrier:** Carl H. Sutton, Department of Neurological Surgery, University of Miami School of Medicine, Miami, FL 33152

RT-3 **Reversibility of the Blood-Brain Barrier:** Ernest N. Albert, Department of Anatomy, The George Washington University Medical Center, Washington, DC 20037

RT-4 **Determinants of Brain Uptake:** Kenneth J. Oscar, US Army Mobility Equipment Research and Development Command, Ft. Belvoir, VA 22060

Discussants: To Be Announced

WEDNESDAY MORNING, NOV. 2, 0830-0915

FIELD SURVEYS

Session J

J-1 0830 **Measurement and Standardization of Electromagnetic Fields in Czechoslovakia:** Jan Musil, Institute of Hygiene and Epidemiology, Srobarova 48, 100 42 Prague 10, Czechoslovakia

J-2 0840 **Measurements of Strong Electromagnetic Fields in Industrial Environments:** P. G. Galliano, Istituto Elettrotecnico Nazionale, Galileo Ferraris, Corso Massimo D'Azeglio 42—I 10125—Torino, Italy

J-3 0850 **Measurement of Electric- and Magnetic-Field Strengths Near Industrial Radiofrequency Heaters:** Maila Hietanen, Pirkko-Liisa Kalliomäki, Institute of Occupational Health, Helsinki, Finland, Pentti Lindfors and Juha Ristilä, General Direction of Post and Telegraphs of Finland Radio Laboratory, Helsinki, Finland, and Kalevi Kalliomäki, University of Oulu, Oulu, Finland

0900
0915- **Discussion**

WEDNESDAY MORNING, NOV. 2, 0915-1030/1055-1225

MULTI-LINGUAL SESSION*

Session K

*This period is reserved for late European submissions. The official languages for this session will be English and Russian

1030-1055 Coffee/Tea Break

1230-1330 Luncheon

WEDNESDAY AFTERNOON, NOV. 2, 1330-1500

RF-HEARING AND OTHER NERVOUS SYSTEM EFFECTS

Session L

L-1 1330 **Threshold Energy for Hearing Microwave Pulses of 10- to 500-μs Duration:** C. K. Chou and A. W. Guy, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

L-2 1340 **Middle-Ear Impairment and Microwave Hearing:** C. K. Chou, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195, and Robert Galambos, University of California, San Diego, School of Medicine, Department of Neurosciences, A-012, La Jolla, CA 92093

L-3 1350 **Eighth-Nerve Derived, Single-Neuron Responses to Acute Microwave Radiation of the Head:** Robert M. Lebovitz and Ronald L. Seaman, Department of Physiology, University of Texas Health Science Center, Dallas, TX 75235

L-4 1400 **The Effect of Microwaves on Crayfish Neurons:** G. Matsumoto, Research Institute of Applied Electricity, Hokkaido University, Sapporo, Japan, and I. Yamaura, Electrotechnical Laboratory, Tanashi Branch, Tokyo, Japan

L-5 1410 **Microwave Effects on Nerve Vitality:** Donald I. McRee, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, and Howard Wachtel, Duke University, Durham, NC 27706

L-6 1420 **The Visually Evoked Electrocortical Response of the Guinea Pig After Microwave-Induced Hyperthermia:** Virginia Bruce-Wolfe, Michelle Mathews, Department of Psychiatry, The Kansas University Medical Center, Kansas City, KS 66103, and Don R. Justesen, Laboratories of Experimental Neuropsychology, Veterans Administration Hospital, Kansas City, MO 64128

1430
1500- **Discussion**

WEDNESDAY AFTERNOON, NOV.2, 1525-1730

SUB-CELLULAR AND CELLULAR EFFECTS

Session M

M-1 1525 **Models of Long-Range Order in Cerebral Macromolecules: Effects of ELF, VHF and UHF Fields in Calcium Binding:** S. M. Bawin, A. R. Sheppard, and W. R. Adey, Environmental Neurobiology Laboratory, UCLA Brain Research Institute, Los Angeles, CA 90024

M-2 1535 **Two Parameters Affecting Radiation-Induced Calcium Efflux from Brain Tissue:** C. F. Blackman, J. A. Elder, C. M. Weil, S. G. Benane, and D. C. Eichinger, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

M-3 1545 **Activity of Membrane-Bound Enzymes Exposed to Amplitude-Modulated 2450-MHz Radiation:** John W. Allis and Madeline L. Fromme, Experimental Biology Division, Health Effects Research Laboratory, Environmental Protection Agency, Research Triangle Park, NC 27711

M-4 1555 **Effects of Microwave Radiation on Erythrocyte Membranes:** Li-Ming Liu and Stephen F. Cleary, Department of Biophysics, Virginia Commonwealth University, Richmond, VA 23298

M-5 1605 **Injury of Cell Membranes in Normal and SV_{40}-Virus Transformed Fibroblasts Exposed in vitro to 2450-MHz Microwave or Water-Bath Hyperthermia (43°C):** Marek Janiak and Stanislaw Szmigielski, Center for Radiobiology and Radioprotection, 00-909 Warsaw, Poland

M-6 1615 **A Comparative Study of the Action of Two Types of Microwave Irradiation on Lipid Metabolism in Mice:** A. Deficis, J. C. Dumas, J. Laurens, and G. Plurien, Ministère de la Défense, Délégation Generale Pur L'Armement, Direction des Recherches et Moyens D'Essais, Service des Recherches, Groupe 9: Biologie et Sciences Humaines, 75996 Paris Armées, France

M-7 1625 **Comparative Effects of Water Bath- and Microwave-Induced Hyperthermia on Cell Survival and Sister Chromatid Exchange (SCE) in Chinese Hamster Ovary (CHO) Cells:** G. K. Livingston, C. C. Johnson, Department of Bioengineering, and L. A. Dethlefsen, Department of Radiology, University of Utah, Salt Lake City, UT 84112

M-8 1635 **Effects of Microwaves on Spermatozoa and Observation of Motility by the Laser Light-Scattering Technique:** Hideaki Shimizu, Kenjiro Sakurai, and Gen Matsumoto, Electrotechnical Laboratory, Tanashi, Tokyo 188, Japan

1645
1725- **Discussion**

THURSDAY MORNING, NOV. 3, 0830-1015

BEHAVIORAL EFFECTS—I

Session N

N-1 0830 **Facial Irradiation of the Freely Responding Macaca mulatta by 9.3-GHz Pulsed Microwaves: A Long-Term Investigation:** R. McAfee, V. A. Hospital, New Orleans, LA 70146, R. Gordon, Tulane University Medical Center, New Orleans, LA, A. Longacre, Jr., J. May, and S. T. Elder, University of New Orleans, New Orleans, LA 70122

N-2 0840 **Skilled Performance by Primates in "Unsafe" RF Environments:** Dennis M. Scholl and Stewart J. Allen, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

N-3 0850 **Performance by Squirrel Monkeys of a Repeated-Acquisition Task After Microwave Irradiation:** T. D. Nelson, Naval Aerospace Medical Research Laboratory, Biomedical Division, Naval Air Station, Pensacola, FL 32508

N-4 0900 **Operant Behavior and Colonic Temperature of Squirrel Monkeys During Microwave Irradiation:** John de Lorge, Naval Aerospace Medical Research Laboratory, Biomedical Division, Naval Air Station, Pensacola, FL 32508

N-5 0910 **The Effects of Psychoactive Drugs and Microwave Radiation on Operant Behavior:** John C. Monahan and W. W. Henton, Bureau of Radiological Health, Division of Biological Effects, Rockville, MD 20852

N-6 0920 **Videotape Observation of Rats During Exposure to 2450-MHz Microwave Radiation:** Michael I. Gage, Ezra Berman, James B. Kinn and George E. Anderson, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

N-7 0930 **Conditional Hyperthermia Induced by Microwave Irradiation or Footshock in Rats is Highly General and Resistant to Extinction:** R. I. Bermant, Department of Psychology, University of Kansas, Lawrence, KS 66045, D. Reeves, and D. R. Justesen, Veterans Administration Hospital, Kansas City, MO 64128

0940
1015- **Discussion**

1015-1040 Coffee/Tea Break

THURSDAY MORNING, NOV. 3, 1040-1210

BEHAVIORAL EFFECTS—II

Session O

O-1 1040 **Operant Behavior of Rats Following Overnight Exposures to Microwaves:** Michael I. Gage, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

O-2 1050 **Behavioral and Physiological Effects on Rats of Chronic, Low-Level 915-MHz Microwave Radiation:** J. A. D'Andrea, O. P. Gandhi, J.

partment of Radiation Biology and Biophysics, School of Medicine and Dentistry, The University of Rochester, Rochester, NY 14642

I-5 1650 **Effects of Pre- and Post-Natal Exposures to 918-MHz Microwave Radiation on Development and Behavior in Rats:** R. B. Johnson, S. Mizumori, D. E. Myers, A. W. Guy, and R. H. Lovely, Bioelectromagnetics Research Laboratory, Departments of Rehabilitation Medicine and Psychology, University of Washington, Seattle, WA 98195

I-6 1700 **Embryotrophic Effects of Pulsed Electrostatic Fields:** Hana Pafková, Institute of Hygiene and Epidemiology, Srobarova 48, 100 42 Prague 10, Czechoslovakia

1710
1740- **Discussion**

TUESDAY EVENING, NOV. 1, 2000-2200

ROUND TABLE ON BLOOD-BRAIN-BARRIER PERMEABILITY EFFECTS

Session RT

Chairman: D. R. Justesen, Veterans Administration Hospital, Kansas City, MO 64128

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RT-3 **Reversibility of the Blood-Brain Barrier:** Ernest N. Albert, Department of Anatomy, The George Washington University Medical Center, Washington, DC 20037

RT-4 **Determinants of Brain Uptake:** Kenneth J. Oscar, US Army Mobility Equipment Research and Development Command, Ft. Belvoir, VA 22060

Discussants: To Be Announced

WEDNESDAY MORNING, NOV. 2, 0830-0915

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0900
0915- **Discussion**

WEDNESDAY MORNING, NOV. 2, 0915-1030/1055-1225

MULTI-LINGUAL SESSION*

Session K

*This period is reserved for late European submissions. The official languages for this session will be English and Russian

1030-1055 Coffee/Tea Break

1230-1330 Luncheon

WEDNESDAY AFTERNOON, NOV. 2, 1330-1500

RF-HEARING AND OTHER NERVOUS SYSTEM EFFECTS

Session L

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L-2 1340 **Middle-Ear Impairment and Microwave Hearing:** C. K. Chou, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195, and Robert Galambos, University of California, San Diego, School of Medicine, Department of Neurosciences, A-012, La Jolla, CA 92093

L-3 1350 **Eighth-Nerve Derived, Single-Neuron Responses to Acute Microwave Radiation of the Head:** Robert M. Lebovitz and Ronald L. Seaman, Department of Physiology, University of Texas Health Science Center, Dallas, TX 75235

L-4 1400 **The Effect of Microwaves on Crayfish Neurons:** G. Matsumoto, Research Institute of Applied Electricity, Hokkaido University, Sapporo, Japan, and I. Yamaura, Electrotechnical Laboratory, Tanashi Branch, Tokyo, Japan

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L-6 1420 **The Visually Evoked Electrocortical Response of the Guinea Pig After Microwave-Induced Hyperthermia:** Virginia Bruce-Wolfe, Michelle Mathews, Department of Psychiatry, The Kansas University Medical Center, Kansas City, KS 66103, and Don R. Justesen, Laboratories of Experimental Neuropsychology, Veterans Administration Hospital, Kansas City, MO 64128

1430
1500- **Discussion**

WEDNESDAY AFTERNOON, NOV.2, 1525-1730

SUB-CELLULAR AND CELLULAR EFFECTS
Session M

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M-2 1535 **Two Parameters Affecting Radiation-Induced Calcium Efflux from Brain Tissue:** C. F. Blackman, J. A. Elder, C. M. Weil, S. G. Benane, and D. C. Eichinger, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

M-3 1545 **Activity of Membrane-Bound Enzymes Exposed to Amplitude-Modulated 2450-MHz Radiation:** John W. Allis and Madeline L. Fromme, Experimental Biology Division, Health Effects Research Laboratory, Environmental Protection Agency, Research Triangle Park, NC 27711

M-4 1555 **Effects of Microwave Radiation on Erythrocyte Membranes:** Li-Ming Liu and Stephen F. Cleary, Department of Biophysics, Virginia Commonwealth University, Richmond, VA 23298

M-5 1605 **Injury of Cell Membranes in Normal and SV_{40}-Virus Transformed Fibroblasts Exposed in vitro to 2450-MHz Microwave or Water-Bath Hyperthermia (43°C):** Marek Janiak and Stanislaw Szmigielski, Center for Radiobiology and Radioprotection, 00-909 Warsaw, Poland

M-6 1615 **A Comparative Study of the Action of Two Types of Microwave Irradiation on Lipid Metabolism in Mice:** A. Deficis, J. C. Dumas, J. Laurens, and G. Plurien, Ministère de la Défense, Délégation Generale Pur L'Armement, Direction des Recherches et Moyens D'Essais, Service des Recherches, Groupe 9: Biologie et Sciences Humaines, 75996 Paris Armées, France

M-7 1625 **Comparative Effects of Water Bath- and Microwave-Induced Hyperthermia on Cell Survival and Sister Chromatid Exchange (SCE) in Chinese Hamster Ovary (CHO) Cells:** G. K. Livingston, C. C. Johnson, Department of Bioengineering, and L. A. Dethlefsen, Department of Radiology, University of Utah, Salt Lake City, UT 84112

M-8 1635 **Effects of Microwaves on Spermatozoa and Observation of Motility by the Laser Light-Scattering Technique: Hideaki Shimizu, Kenjiro Sakurai, and Gen Matsumoto, Electrotechnical Laboratory, Tanashi, Tokyo 188, Japan**

1645
1725- **Discussion**

THURSDAY MORNING, NOV. 3, 0830-1015

BEHAVIORAL EFFECTS—I
Session N

N-1 0830 **Facial Irradiation of the Freely Responding** Macaca mulatta **by 9.3-GHz Pulsed Microwaves: A Long-Term Investigation:** R. McAfee, V. A. Hospital, New Orleans, LA 70146, R. Gordon, Tulane University Medical Center, New Orleans, LA, A. Longacre, Jr., J. May, and S. T. Elder, University of New Orleans, New Orleans, LA 70122

N-2 0840 **Skilled Performance by Primates in "Unsafe" RF Environments:** Dennis M. Scholl and Stewart J. Allen, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

N-3 0850 **Performance by Squirrel Monkeys of a Repeated-Acquisition Task After Microwave Irradiation:** T. D. Nelson, Naval Aerospace Medical Research Laboratory, Biomedical Division, Naval Air Station, Pensacola, FL 32508

N-4 0900 **Operant Behavior and Colonic Temperature of Squirrel Monkeys During Microwave Irradiation:** John de Lorge, Naval Aerospace Medical Research Laboratory, Biomedical Division, Naval Air Station, Pensacola, FL 32508

N-5 0910 **The Effects of Psychoactive Drugs and Microwave Radiation on Operant Behavior:** John C. Monahan and W. W. Henton, Bureau of Radiological Health, Division of Biological Effects, Rockville, MD 20852

N-6 0920 **Videotape Observation of Rats During Exposure to 2450-MHz Microwave Radiation:** Michael I. Gage, Ezra Berman, James B. Kinn and George E. Anderson, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

N-7 0930 **Conditional Hyperthermia Induced by Microwave Irradiation or Footshock in Rats is Highly General and Resistant to Extinction:** R. I. Bermant, Department of Psychology, University of Kansas, Lawrence, KS 66045, D. Reeves, and D. R. Justesen, Veterans Administration Hospital, Kansas City, MO 64128

0940
1015- **Discussion**

1015-1040 Coffee/Tea Break

THURSDAY MORNING, NOV. 3, 1040-1210

BEHAVIORAL EFFECTS--II
Session O

O-1 1040 **Operant Behavior of Rats Following Overnight Exposures to Microwaves:** Michael I. Gage, Health Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC 27711

O-2 1050 **Behavioral and Physiological Effects on Rats of Chronic, Low-Level 915-MHz Microwave Radiation: J. A. D'Andrea, O. P. Gandhi, J.**

L. Gehrich, L. Astle, C. H. Durney, J. L. Lords, J. Nelson, and C. C. Johnson, University of Utah, Salt Lake City, UT 84112

O-3 1100 **Behavioral and Physiological Effects on Rats of Chronic, Square-Wave Modulated Microwave Radiation:** Richard H. Lovely, D. Myers, Departments of Rehabilitation Medicine and Psychology, Thomas Sparks, and Arthur W. Guy, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

O-4 1110 **Combined Effects on Behavior of Low-Level Microwave Radiation and Dextroamphetamine:** J. R. Thomas and Georgia Maitland, Behavioral Sciences Department, Naval Medical Research Institute, Bethesda, MD 20014

O-5 1120 **Comparative Study of the Action of Three Microwave Fields upon the Behavior of the White Rat:** B. Servantie, J. Gillard, A. M. Servantie, J. Obrenovitch, G. Bertharion, J. C. Perrin, B. Creton, and G. Plurien, Hôital Ste Anne, CERB, 83800 Toulon Naval, France

O-6 1130 **Behavior of Chicks on an FT-30-Sec Schedule of Reinforcement when Exposed to Low-Power 450-MHz Fields Amplitude Modulated in the EEG Range:** P. M. Sagan and R. G. Medici, Environmental Neurobiology Laboratory, Brain Research Institute, University of California, Los Angeles, CA 90024

1140
1210- **Discussion**

1230-1330 Luncheon

THURSDAY AFTERNOON, NOV. 3, 1330-1530

LOW FREQUENCY FIELD EFFECTS
Session P

P-1 1330 **Hematologic and Serum-Chemistry Evaluations in Rats Exposed to 60-Hz Electric Fields:** H. A. Ragan, M. J. Pipes, W. T. Kaune, and R. D. Phillips, Battelle Pacific Northwest Laboratories, Richland, WA 99352

P-2 1340 **Chronic Exposure of Primates to ELF Electric and Magnetic Fields:** J. D. Grissett, Naval Aerospace Medical Research Laboratory, Naval Air Station, Pensacola, FL 32508

P-3 1350 **Behavioral Sensitivity of an Avian to 60-Hz AC and to DC Magnetic Fields:** Rex L. Clarke, Department of Psychology, University of Kansas, Lawrence, KS 60044, and Don R. Justesen, Veterans Administration Hospital, Kansas City, MO 64128

P-4 1400 **Effects of ELF Fields on the Slime Mold Physarum polycephalum: Evidence for Depression of Cellular Function and for a Transferable Factor:** B. Greenebaum, E. M. Goodman, and M. T. Marron, Division of Science, University of Wisconsin-Parkside, Kenosha, WI 53141

P-5 1410 **Biological Effects of 60-Hz Electric Fields on Growth and Metabolic Status of Rats:** R. D. Phillips, J. H. Chandon, L. Lang and D. I. Hilton, Battelle Pacific Northwest Laboratories, Richland, WA 99352

P-6 1420 **ECG and Heart-Rate Response of Rats Exposed to 60-Hz Electric Fields:** D. I. Hilton, J. H. Chandon, and R. D. Phillips, Biology Department, Battelle Pacific Northwest Laboratories, Richland, WA 99352

P-7 1430 **Behavioral and Physiological Effects on Rats of Chronic Exposure to Strong 60-Hz Electric Fields:** M. Smith, J. A. D'Andrea, O. P. Gandhi, and C. C. Johnson, Departments of Electrical Engineering and Bioengineering, University of Utah, Salt Lake City, UT 84112

P-8 1440 **A Behavioral Response to High-Strength 60-Hz Electric Fields:** D. L. Hjeresen and R. D. Phillips, Biology Department, Battelle Pacific Northwest Laboratories, Richland, WA 99352

1450
1530- **Discussion**

1530-1555 Coffee/Tea Break

THURSDAY AFTERNOON, NOV. 3, 1555-1755

HEMATOLOGIC AND IMMUNOLOGIC EFFECTS
Session Q

Q-1 1555 **Long Term Follow-up of Macaca mulatta Exposed to High Power Levels of 15-, 20- and 26-MHz Radio-Frequency Radiation:** Jerome H. Krupp, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

Q-2 1605 **Effects of Radio Waves on Growth, Hematology and Histology of Mice:** James C. Lin, John C. Nelson, Merlin E. Ekstrom, and Song H. Nam, Departments of Electrical Engineering, Comparative Medicine, and Pathology, Wayne State University, Detroit, MI 48202

Q-3 1615 **Response of Lymphocytes in vitro to 30-MHz Radio-Frequency Fields:** Richard H. Lovely, Thomas J. Sparks, and Arthur W. Guy, Bioelectromagnetics Research Laboratory, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

Q-4 1625 **Differential Effects of RF Radiation on Subpopulations of Murine Lymphocytes:** Robert P. Liburdy, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

Q-5 1635 **Chronic Exposure of Rats to 425- or 2450-MHz Microwave Radiation: Effects on Lymphocytes:** Ralph J. Smialowicz, James B. Kinn, Claude M. Weil, and Thomas R. Ward, Experimental Biology Division, Health Effects Research Laboratory, Environmental Protection Agency, Research Triangle Park, NC 27711

Q-6 1645 **Alteration of Cell-Mediated Immunity to Local Microwave Hyperthermia (43 °C) of Guerin Epithelioma in Rats:** Stanislaw

Szmigielski and Marek Janiak, Center for Radiobiology and Radioprotection, 00-909, Warsaw, Poland

Q-7 1655 Further Characterization of Microwave-Induced Changes in Subpopulations of Lymphoid Spleen Cells in the Mouse with Particular Reference to Complement-Receptor-Bearing Lymphocytes: Wieslaw Wiktor-Jedrzejczak, Postgraduate Center, Military School of Medicine, 00-909 Warsaw, Poland, Aftab Ahmed, William M. Leach, Przemyslaw Czerski, Howard Cyr, and Kenneth W. Sell

Q-8 1705 The Relationship of Thermal Stress to Immune-System Response in Mice Exposed to 2.6-GHz Radio-Frequency Radiation: Jerome H. Krupp, Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks AFB, TX 78235

1715
1755- Discussion

FRIDAY MORNING, NOV. 4, 0830-1015

HYPERTHERMIA--APPLICATORS AND TECHNIQUES

Session R

R-1 0830 Design of Aperture Sources for Deep Heating by Electromagnetic Energy: Henry S. Ho, U.S. Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20857

R-2 0840 Applicators for Inducing Hyperthermia by RF Energy in Embedded Tumors: Kun-Mu Chen and Sutus Rukspollmuang, Department of Electrical Engineering and Systems Science, Michigan State University, E. Lansing, MI 48824

R-3 0850 Design of Miniature Microwave Applicators for Clinical Hyperthermia: A. Y. Cheung and G. M. Samaras, Martha V. Filbert Radiation Center, Department of Radiology, University of Maryland School of Medicine, Baltimore, MD 21201

R-4 0900 A 915-MHz Exposure System for Hyperthermal Treatment of Cancer: C. C. Johnson, H. Plenk, and Carl H. Durney, Department of Bioengineering, University of Utah, Salt Lake City, UT 84112

R-5 0910 Experimental and Numerical Studies of Temperature in a Human Leg Heated by Diathermy: A. F. Emery, Department of Mechanical Engineering, J. Stonebridge, Department of Rehabilitation Medicine, M. Sekins, Department of Mechanical Engineering, and J. F. Lehmann, Department of Rehabilitation Medicine, University of Washington, Seattle, WA 98195

R-6 0920 A Study of Leakage Fields near Therapeutic 915- and 2450-MHz Applicators as Applied to Models and as Used in Human Exposures: Justus F. Lehmann, A. W. Guy, and J. Stonebridge, Department of Rehabilitation Medicine RJ-30, University of Washington School of Medicine, Seattle, WA 98195

R-7 0930 Localized Embedding of Labelled Microspheres by Microwave Heating in Tissues of Hypothermic Dogs: V. Popovic and Pava Popovic, Department of Physiology, Emory University Medical School, Atlanta, GA 30322

0940
1015- Discussion

1015-1040 Coffee/Tea Break

FRIDAY MORNING, NOV. 4, 1040-1245

HYPERTHERMIA- CANCER THERAPY

Session S

S-1 1040 The Effects of Hyperthermia, Microwave Radiation, and Ascorbic Acid on the Metabolism of Ehrlich Ascites Carcinoma Cells in vitro: G. E. Piontek, C. A. Cain, and J. A. Milner, Department of Bioengineering, University of Illinois, Urbana, IL 61801

S-2 1050 Effects in vivo of Combined Microwave and X-Ray Treatment on a Transplantable Mouse Mammary Adenocarcinoma: Barbara J. Clarke, Department of Biology, The American University, Washington, D.C. 20016

S-3 1100 Combined Effects of Pulsed Magnetic Radiation (Diapulse) and Chemotherapy on Tumor-Bearing Mice: Brian West and William Regelson, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA 23298

S-4 1110 The Response of Pig Skin to Combined X-Irradiation and Microwave Heating: S. B. Field and J. W. Hand, M.R.C. Cyclotron Unit, Hammersmith Hospital, Ducane Road, London W12 OHS, England

S-5 1120 Destruction of Solid Tumors by Heating with Radio-Frequency Energy: J. A. Dickson, The University of Newcastle Upon Tyne, Cancer Research Unit, Department of Clinical Biochemistry, The Royal Victoria Infirmary, Newcastle Upon Tyne NE1 4LP, England

S-6 1130 Treatment of Tumors with 69-cm Diathermy: H. Ollendiek, Ludwigstrasse 19, 6350 Bad Nauheim, Federal Republic of Germany

S-7 1140 Techniques and Results of Using Microwaves and X-Rays for the Treatment of Tumors in Man: William T. Joines, Electrical Engineering Department, Duke University, Raymond U, Radiology Department, Duke University and V. A. Hospital, Thomas K. Noell, Lowell S. Miller, Radiology Department, Duke University, and Kent T. Woodward, Radiology Department and V. A. Hospital, Durham, NC 27706

S-8 1150 Effects of 434-MHz Electromagnetic Waves on Human Cancers: J. A. G. Holt, Institute of Radiotherapy and Oncology of Western Australia, 21 McCourt Street, Leederville, W.A. 6007, Australia

1200
1240- Discussion

1245-1345 Luncheon

Senator FORD. Thank you very much.

The next witness will be Capt. Frank H. Austin, Jr., Assistant Director, Environmental and Life Sciences, Office of the Director of Defense Research and Engineering.

STATEMENTS OF CAPT. FRANK H. AUSTIN, JR., MC USN, ASSISTANT DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES, OFFICE OF THE DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING; MAJ. LAWRENCE E. LARSEN, MC USA, CHIEF, BIOPHYSICS, DEPARTMENT OF MICROWAVE RESEARCH, WALTER REED ARMY INSTITUTE OF RESEARCH; CAPT. PAUL E. TYLER, MC USN, DIRECTOR, EMR PROJECT OFFICE, NAVAL MEDICAL R. & D. COMMAND, BETHESDA, MD.; AND JOHN C. MITCHELL, CHIEF, RADIATION PHYSICS, RADIATION SCIENCES DIVISION, U.S. AIR FORCE SCHOOL OF AEROSPACE MEDICINE, BROOKS AIR FORCE BASE, TEX.

Captain AUSTIN. Mr. Chairman, we would like to be a panel.

Senator FORD. Of course each of you may submit your prepared testimony for the record. If you wish, you may highlight your prepared statements.

I would hope that each of you would identify yourselves as you start your statement.

Captain AUSTIN. I am Capt. Frank Austin. We have provided a biography to your staff of each of the people who are going to be present today. We have also submitted written testimony. Our oral testimony today will be much shorter than that. We decided not to use the viewgraphs. Each of us have made copies of the graphs that are in the testimony we have submitted. We have extra copies to pass out to you right now.

It is a privilege to report to the committee, Mr. Chairman, concerning the DOD program for research and development on the biomedical effects of electromagnetic radiation—EMR.

I am Capt. Frank H. Austin, Jr., MC USN, from the Office of the Director of Defense Research and Engineering. With me today are Major Larsen, U.S. Army, Captain Tyler, U.S. Navy, and Mr. Mitchell, U.S. Air Force. They will describe for you the integrated triservice research and development program, and respond to your questions concerning it. My preliminary remarks will be brief.

We understand that the thrust of these hearings is to:

(a) Determine whether there exists any evidence that current regulations for EMR are inadequate to protect exposed persons from deleterious health effects;

(b) Survey the present state of the scientific knowledge;

(c) Review on-going research;

(d) Hear expert opinions regarding potential deleterious effects of various radiations; and

(e) Hear opinions as to what further research may need to be done.

Our statements have been directed to provide some answers for these concerns from the viewpoint of the Defense Department.

We also understand you are concerned with the management of regulations and perhaps regulatory agency organization. The scientific panel before you today is not structured to address DOD opinion or policy on Federal regulatory agencies or their organization.

In response to written questions in this area from the committee, Dr. William J. Perry, Director of Defense Research and Engineering, provided a DOD response, and I have appended a copy for entry in the record.[1]

Dr. Perry's response in summary:

(a) Regarding the impact on DOD of jurisdictional changes, inception of new agencies, and transfers of regulatory authority; the overall efforts within DOD have certainly increased in recent years, but the programs have resulted in a high degree of cooperative interdependency between the services and other Federal agencies such as the Bureau of Radiological Health of the Food and Drug Administration, and the National Institute of Occupational Health and Safety, coordinated by the Office of Telecommunications Policy—OTP. Our representatives meet with these agencies on a regular basis to exchange scientific and technical data.

(b) Regarding possible confusion concerning respective responsibilities of State and Federal agencies; we have experienced no significant problems.

(c) Regarding thoughts on how present regulation of radiation programs could be improved; the clear definition of jurisdiction of each Federal agency would help prevent confusion in the future when new nonionizing radiation standards are proposed.

(d) Regarding funding adequacy; the services have generally proposed adequate funding for execution of the triservice EMR research plan. Budgetary realignments within DOD may result in some program extensions of the research plan.

(e) Regarding proposals to consolidate all Federal radiation activities into one Federal agency; the removal of defense systems biomedical research from DOD would be detrimental to the timely development of weapons systems, and is therefore not supported.

Now if I may, some general comments about our DOD triservice EMR bioeffects research plan. The plan was prepared in June 1975 and has been updated with annual program reviews since. The Department of Defense is the Nation's largest user of nonionizing electromagnetic radiation devices including a wide variety of reconnaissance, surveillance, and communications systems in air, sea, and ground operations.

The systems range in frequency from 45 Hz to 100 GHz with the majority having service or system specific parameters, that is, frequency, power, pulse rate, pulse width, and mode of operation. These variables all contribute somewhat differently to the potential biological injury problem, so human hazard assessments require multiple parameter studies.

Considerable progress has been made in the coordinated electromagnetic radiation—EMR—research program to meet DOD requirements and the service witnesses will detail this progress in their reports.

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[1] See p. 893.

The principal objective of the EMR research program is to maximize personnel safety while maintaining operational readiness. The program is organized to apply a practical level of effort to achieve answers to logical questions in a priority sequence. While proceeding in this manner, it is recognized that many isolated reports of so-called low-level bioeffects may not be immediately addressed by DOD researchers. On the other hand, the program will provide the best available collective data base of EMR bioeffects to make timely and appropriate decisions in support of specific DOD systems operations. This means, in effect, that through this program, each service can provide the best guidance available at any point in time to prepare and/or support everything from environmental impact to detailed operating procedures concerning any of their EMR emitters.

The principal advantages of this coordinated research program are: (1) to avoid any unnecessary duplicative efforts, (2) to maximize use of EMR research manpower and facilities, (3) to focus collective competence to resolve the more difficult high priority problems in the shortest time.

Such a joint research program does not replace, but rather complements the responsibilities of each service to provide detailed support to its unique EMR systems development and operation. For example, shipboard and airborne systems pose entirely different problems than fixed site operations. Each of the services must work within its own chain of command and resources to provide timely inputs on any participation of the service's research team with other non-DOD scientific institutions and agencies, the optimum balanced national program will be assured.

I will leave to the other panel members the discussion of EMR personnel exposure standards, scientific data gaps, discussion of biotechnology research areas, defense systems support research, and other technical aspects of the individual service programs.

In conclusion, the nonionizing electromagnetic radiation area is a large, complex multiparametered problem that has captured the interest of consumer protection groups, environmentalists, regulatory agencies, legislators, and scientists from around the world. There are national and international concerns over the presently accepted safe level.

DOD's responsibilities as a major user of the EMR spectrum encompass safety criteria from design through production to operational employment. Legislation on environmental protection, occupational safety and health, and concern for general population safety necessitates a strong service specific R. & D. program to support military systems development and operational applications while assuring the protection of the EMR system operator and the general public.

I have one additional statement that wasn't in my written testimony.

The scientific evidence available today is inconclusive to support changing the EMR standard either upward or downward. The ultimate goal of our research is to make this determination.

Our witnesses today, I hope, will help answer some of the details about that.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND THE ANSWERS OF CAPTAIN AUSTIN

Question 1. (a) To what extent are Defense Personnel exposed to ionizing radiation from diagnostic medical and dental x-rays? (b) What is the average annual exposure from such sources? (c) Has average exposure increased over the last few years? (d) Is each individual exposure monitored for intensity and measurements recorded for the patient's medical history? (e) How well trained are the operators of X-ray machines? (f) What requirements are they supposed to meet? (g) How often is X-ray equipment checked for leakage or other defects?

Answer. (*a*) The Department of Defense provides diagnostic medical and dental x-rays to all of its Department of Defense personnel as authorized by current regulations. Diagnostic radiology is utilized as an integral part of the health care system. In maintaining the highest quality of health care, radiography is used on a comparable basis with civilian institutions. Chest x-rays are also used as part of the military's preventive medicine program of periodic physical examinations. The frequency of these physical examinations for individuals vary depending on age and type of duty. For example, personnel on flight status receive annual physicals while others vary from one to four years between examinations.

(*b*) We do not collect, maintain, or review data which would provide a direct estimate of the average annual exposure to our personnel. The Department of Defense has and is participating in a joint State/Federal program, labeled Project NEXT (Nationwide Evaluation of X-Ray Trends) administered by the Bureau of Radiological Health (BRH). The program involves the measurement of exposure at skin entrance delivered to a standardized patient under actual clinical conditions for 12 common radiographic procedures (nine medical and three dental). Data collected for the period July 1, 1973 through December 31, 1976 are tabulated below:

Projection	Number of samples	(MR) exposure at skin entrance			
		Mean	Minimum	Maximum	Median
Chest (P/A)	241	34	1	375	16
Skull (lateral)	49	273	39	1, 505	218
Abdomen (KUB)	119	643	5	2, 488	543
Retrograde pyelogram	16	536	62	1, 055	591
Scout film (cysto units) (A/P):					
Thoracic spine (A/P)	5	796	67	1, 562	909
Cervical spine (A/P)	12	205	14	1, 122	129
Lumbo-sacral spine (A/P)	80	777	40	3, 012	616
Full spine (A/P)	3	625	414	827	635
Feet (weight bearing):					
(D/P) (podiatrist only)	15	99	2	463	18
Dental bitewing	156	307	15	2, 146	181
Dental periapical	129	294	15	1, 956	198
Dental cephalometric	3	89	36	151	81

Note.—The data are consistent with exposures delivered by civilian institutions tested and are very favorable for the more commonly used exposures to which the greatest numbers of our people are exposed.

(*c*) Analysis of data on an annual basis has not been performed for DOD installations. Awareness of the need to reduce exposures on the part of physicians and X-ray technicians as well as our aggressive upgrading of X-ray equipment which complies with Title 21, CFR, Subchapter J should further reduce exposures to patients for diagnostic purposes.

(*d*) The Department of Defense does not currently determine or record exposure intensity for each individual during radiographic procedure. To do so, would involve not only the expenditure of significant sums of money to procure equipment, train technicians, and accomplish administrative tasks, but would likely result in overcrowding of heavily used radio-graphic facilities. Our continued participation in nation wide exposure evaluation programs, and the enforcement of controls over the radiographic processes will adequately serve to reduce exposures to radiation for medical purposes.

(e) All Department of Defense personnel receive specialized training before being allowed to function as X-ray operators. While the specific training varies slightly between the services, all receive training and supervised experience to qualify the individual to become certified by the American Society of Radiologic Technologists.

(f) As noted above the training varies slightly between the three services. For example in the Air Force health care radiography is performed by personnel assigned in two Air Force Specialties—903X0, Radiologic Specialist, Technician, and Superintendent, and the 981X1, Dental Specialist, Technician, and Superintendent. The duties, responsibilities, and specialty qualification for these specialties are shown in Attachments 1 through 6 taken from AFG 39–1. Airman Classification Guide.[1]

Prior to assignment to permanent duties in Medical or Dental Radiography, individuals are provided extensive training. In the case of Radiologic Technicians, candidates receive intensive academic training in a phase I course of 14 weeks duration at the USAF School of Health Care Sciences, located at Sheppard AFB, Tex. Following Phase I, candidates are assigned to Phase II training of 9 months duration conducted at one of the major USAF medical facilities. Upon successful completion of these two Phases, the individual is qualified to independently perform medical radiography. In order to advance in grade and responsibility, the individual must become fully qualified in his Air Force Specialty. Accomplishing this requires successful completion of Phase III training, which consists of a program of on-the-job training, self study, and comprehensive testing.

Candidates in Dental specialties begin by attending a 10-week course also conducted at the USAF School of Health Care Sciences. This course includes formal training in Dental Radiography. Upon completion. the individual is assigned to a permanent duty station and embarks on a four to six month period of on-the-job training and Career Development Courses. Upon successful completion he is fully qualified to perform his duties, including Dental Radiography.

In the case of both specialties, particular emphasis is placed on radiation protection including the use of gonadal shields, the utilization of proper technique, and the undesirability of repeat exposures.

The Navy's program for X-ray Technologists is accredited by the American Society of Radiologic Technologists. The course work consists of:

(a) Six months didactic course (8 hours per day) covering: Electronics (including basic physics), mathematics, ethics, anatomy and physiology, film developing techniques, radiologic technology, special procedures, radiation biology, radiation safety, basic principles in Nuclear Medicine Technology, and basic principles in radiation therapy.

(b) Six months clinical training under direct supervision of a board-certified radiologist.

(c) At the completion of an additional year of training under the supervision of a board-certified radiologist the trainee is eligible to apply for certification by the American Society of Radiologic Technologists.

The program is also accredited by the George Washington University, Washington, D.C. The student completing the Navy's X-ray Technologist Course and 6 credit hours in English, 3 credit hours in Humanities, and 3 credit hours in Social Sciences meets the minimum requirements for an Associate Degree in Sciences.

Curriculum is updated according to the reommendations of the American Society of Radiologic Technologists. All technologists' instructors and faculty members, are registered technologists.

Similar procedures are followed by the Army.

(g) X-ray equipment is maintained and evaluated for radiological safety according to a multi-faceted approach. In addition to in-house quality control evaluations, x-ray equipment is checked once every six months for proper operation and calibration according to instructions provided by the manufacturer in accordance with Title 21, Sub-chapter J of the CFR. In addition, once every three years or as indicated by modification or repairs which would significantly affect radiological protection all x-ray machines and facilities are evaluated for radiological safety and performance by a Health Physicist or an individual qualified in performing the evaluation.

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[1] Available in committee files.

Question 2. Are you familiar with Dr. Irwin Bross' work on the hazards of low-level ionizing radiation—the Tri-State survey? Has this affected your thinking on the need for routine exposure to x-rays?

Answer. Yes; I am familiar with Dr. Bross' work on the hazards of low level ionizing radiation.

The Department of Defense along with other Federal and civilian agencies is concerned with utilizing medical and dental diagnostic radiology to the maximum benefit of the patient. In keeping with this concern, DOD representatives participated in the development of Federal Guidance Report No. 9, "Radiation Protection Guidance for Diagnostic X-Rays", June 1976 (enclosure 7) prepared by the Interagency Working Group on Medical Radiation for the Federal Radiation Council (sic).[1] The Department of Defense endorses the recommendations of this report and intends to implement its provisions through revised directives.

Question 3. What ionizing radiation exposure levels are associated with the Navy's nuclear submarine and surface vessel operations, and how carefully is personnel exposure information being gathered?

Answer. All persons associated with Navy nuclear propulsion plant operations wear monitoring badges to measure the radiation exposure they receive. The results of this monitoring are carefully recorded and reviewed to ensure that an accurate record is made of the radiation exposure received by each monitored individual. These records are audited at least semiannually by persons not directly responsible for maintaining them, such as Squadron Medical Officers, and are inspected annually by Fleet Officers independent of the ship. Radiation levels in nuclear ships are also checked on a frequent basis using portable radiation survey instruments.

The results of this monitoring have consistently shown personnel radiation exposures associated with naval nuclear propulsion plant operations to be very low. No one associated with naval nuclear propulsions plants has received radiation exposure in excess of federal limits in the last 10 years.

Question 4. In the past, the Air Force has exposed some pilots to ionizing radiation by requiring them to obtain samples of contaminated air from mushroom clouds after nuclear test explosions. In another instance, a division of Army troops was marched off across radioactive ground immediately after an atom bomb test in 1954 or 1955. Have follow-up studies been conducted to monitor health effects of either exposure? Please provide citations to published reports and brief descriptions of results.

Answer. During atmospheric weapons tests, cloud sampling was conducted by the Air Force using select groups of aircrew members. To the best of our knowledge, there was no special program, other than regular annual flying physicals to follow-up on the individual's participating in cloud sampling.

No follow-up studies have been conducted. Presently the Department of Defense is in the process of reviewing historical records and data on personnel involved with these tests to determine the need for follow-up studies.

Question 5. Two studies done at Johns Hopkins University have apparently shown that no correlation exists between paternal microwave exposure and mongoloid offspring. According to an article by Paul Brodeur in the New Yorker, however, the second study "suggests that men exposed to the emanations of radar have significant increase in the number of chromosomal abnormalities in their blood." Please comment on this, citing any appropriate references.

Answer. The cytogenic study at Johns Hopkins University has been summarized by the principal investigator as follows:[2]

"To confirm or reject a possible association of Down's syndrome with maternal medical radiation and paternal radar exposure observed in a previous investigation, a replication study was conducted on parents of 300 'Current Series' cases and controls born 1962–1968 and 1945. Validation of military service and radar exposure was undertaken for all Original and Current Series fathers (involving 791 cases, controls and new matches) and chromosomes studied on 159 radar exposed and unexposed fathers. Current Series findings confirm the association with advancing maternal age and lack of a similar paternal age relationship, but show no case-control differences in parental (maternal or paternal) medical radiation or paternal radar exposure. Combining the series still yielded no significant case-control differences in fathers' radar exposure or military service, although slightly more (NSD) Army service was observed in case fathers of each series. A suggestion of more chromosome aberrancy in radar exposed fathers of the Combined Series must be interpreted with caution. Whether the apparent association indicates greater chromosome fragility with microwave exposure or is otherwise biologically meaningful, or is just spurious, requires more definitive, longitudinal studies."

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[1] The report referred to is available from EPA. EPA document number EPA 520/4–76–012, entitled "Recommendations on Guidance for Technic to Reduce Unnecessary Exposure from X-ray Studies in Federal Health Care Facilities."

[2] Final Report DADA–17–69–C–9154, Bernice Cohen, Johns Hopkins University School of Public Health, Baltimore, Md.

Significant differences were found only when "near" and "definitely" exposed groups were pooled and then predominantly in only one of the four classes of abnormality. The one class included possible artificial findings due to methods of tissue preparation. The studies cited, serve to justify more detailed inevstigations to resolve the role of technical error, chromosome fragility and the relationship to microwave exposure.

Question 6. You have mentioned the need for improved bioeffects instrumentation. In your opinion, how reliable are findings which are based on studies that have not used equipment as accurate as that which has recently been developed? Are most independent (non-military) studies subject to this criticism?

Answer. The need for adequate bioeffects instrumentation is absolutely critical for meaningful interpretation of microwave studies in biosystems. For example, it is well known that microwave radiation can cause heating within the interior of dielectric (i.e., non-metallic) objects. The spatial distribution of such heating depends upon field induction and thermal properties within the object. The geometry and electromagnetic properties of the object in turn determine how microwave exposure will induce heat producing fields in the interior. Therefore, the two basic actions are field induction and subsequent heating within the interior of the object.

Except for very simple and model systems, these basic actions of microwave radiation are not predictable from calculations. Empirical studies are necessary. However, it has not been possible until very recently to make temperature measurements within biosystems during microwave exposure. The reasons for this important technological shortage are complicated. However, the end result is easily expressed. Conventional thermometric methods applied in microwave measurements have been shown to seriously alter the pattern and field induction and grossly distort the pattern of heating. In fact, fields are concentrated at the temperature sensor such that up to 100 times more power is deposited at that location than would be the case if the sensor were not present. Thus, the prime biological variable of temperature is not available or controllable. Consequently, conclusions drawn about biochemical or physiological effects which depend upon temperature are at best suspect and probably not valid.

A similar situation exists for the direct measurement of field induction in biosystems. No suitable measurement system presently exists. As a result, we can describe the microwave environment only in terms of radiation launched into space where the biosystem might be located. The obviously critical parameters of energy coupling and spatial distribution of induced fields are missing. The factors determine exposure conditions for internal organs. As a result, reproducible results are distressingly uncommon. Of course, these criticisms apply equally well to research outside of the DOD setting. Indeed, I think it is fair to state that DOD has lead the discipline in the development of temperature sensors suitable for use in microwave environments. These development programs will produce measurement systems that will be available to the civilian as well as the military research community.

Question 7. Are you aware of any employees of the DOD who have incurred injuries and received compensation as the result of exposure to excessive non-ionizing radiation? What were the circumstances?

Answer. The Department of Defense is aware of some former DOD personnel who have claimed injuries from exposure to non-ionizing radiation. In one case it is known that the Veterans' Administration allowed disability compensation to a former Navy enlisted man for cataracts, but denied his claim for other injuries. We are also aware of an out-of-court settlement by industry with a former Air Force enlisted man; again, for cataracts. It is also understood that a former Navy employee has filed a claim against some equipment manufacturers as a result of his pancreatic cancer. Since these claims for compensation have not been filed with Department of Defense, details of these cases and circumstances of the settlements are unknown.

Question 8. List the military non-ionizing radiation technologies being developed which could have significant impacts on the civilian sector, both from an economic and public health point of view. (lasers, microwave range finders, communications technology, etc.)

Answer. Mode locked, ultrashort (picosecond) pulse lasers will vastly improve military and civilian communication systems. Near infrared and ultraviolet lasers will have civilian applications in medical treatment, bloodless surgery and chemistry research. Military developed safe exposure levels and protective laser eyewear are available for civilian adoption.

Radar technology including RF generators producing extremely high frequencies (Gigahertz) radiation are essential for national defense radar surveillance. They will be adapted to civilian needs in commercial air traffic control and FAA landing systems.

The subject of emerging technology for diagnostic and scientific medical application if microwave and RF radiation is an item of great importance in current research. The applications I could cite run the gamut from promising basic research to rather speculative therapeutic applications. Research in the former category includes the use of microwave and RF energy to measure the functional status of cells and organs. This type of application makes use of the fact that noninvasive electromagnetic measurment of the frequency dependent properties of cells appears to directly interrogate physiological properties of the cell membrane. There is the distinct possibility that this type of information may be implemented in a system with imaging capabilities. If this should become a reality, then noninvasive analysis of cellular functional status in deep organs such as heart, liver and kidney may be presented as images. The potential diagnostic value is great in that this type of information is not available with present medical imagery methods such as x-ray and ultrasound.

Question 9. To what extent does DOD utilize laser devices? What is the status of research into the biological effects associated with lasers?

Answer. The DOD uses laser devices in actual air operations as well as in supporting operations on the ground and in laboratories. These applications include communications, range finders, target designators, target surveillance, target acquisition and tracking, countermeasures, systems research and development, and laser weapons development and testing. It is anticipated the use of lasers in the DOD will increase as research uncovers new applications.

Both the Army and Air Force have an active research program on the biological effects of lasers. This program has been conducted primarily at the USAF School of Aerospace Medicine (SAM) and the Letterman Army Institute of Research. The program has been aimed at maximizing personnel safety while maintaining operational readiness. As such, the investigative programs have been confined exclusively to studies concerning the effects of laser radiation on the eye, easily the most sensitive organ, on the skin, which, along the eye, are the most likely organs to receive laser radiation. The results of the military programs have played and continue to play a significant role in the establishment of safe exposure levels for laser radiation for DOD as well as other agencies both nationally and internationally, including the American National Standards Institute (ANSI) which has developed the most widely recognized laser safety standard in the free world.

Current DOD studies are concentrated in the main on the effects of laser radiation on the eye and visual function. These investigations are part of a coordinated DOD research plan that has been designed to maximize the use of manpower and facilities, focus collective competence to resolve more difficult priority problems, and maintain a creditable position with the ANSI, concerned government groups such as the Bureau of Radiological Health (BRH), and the Occupational Safety and Health Administration (OSHA).

Question 10. During a 2-day seminar in 1975, the Office of Telecommunications Policy described eight studies demonstrating changes in genes from microwave exposure. These included: birth defects in mouse fetuses; structural defects in darkling beetles irradiated as pupae; death of zebra fish embryos at non-thermal intensity levels; delays in the onset of normal cell division in slime mold; and chromosomal abnormalities in kangaroo rat cell cultures. Earlier studies performed by Dr. John Heller at the New England Institute for Medical Research showed: chromosomal abnormalities in garlic root tips after exposure at nonthermal levels; mutation in mammalian cells; four different frequencies of low level microwaves which produced mutations in fruit flies.

Would the Department of Defense please describe whether it feels these studies are valid, providing appropriate documentation? What studies are you currently performing that relate to these experiments?

Answer. The Electromagnetic Radiation Management Advisory Council (ERMAC) held a 2 day seminar in August 1975 on Hereditary, Growth and Developmental Effects of Non-Ionizing Radiation.[1] There were 15 separate investigators who presented their research, and of these 15 investigators only 6 discussed research involving chromosomes or genes.

Dr. Berman's mutagenic studies with mice and rats showed no genetic alterations. Dr. Hungate also reported negative results using bacterial cells. Dr. Braver using fruit flies (*Drosophilia*) showed no genetic changes. While Dr. Anderson discussed his procedure to evaluate the bacterium E. coli, for mutations, he did not present any research conclusions. Dr. Elder as part of his studies evaluated blood cells from irradiated animals for chromosomal aberrations and found no change from control animals.

The one study which showed an indication of genetic changes was that by Dr. Yao using 2 strains of kangaroo rat cell cultures which found that after 20 passages through cell cultures strain RH5 showed some chromosomal alterations. At the same time, the cell line RH16 showed no chromosomal changes.

In evaluating these genetic studies the ERMAC Report[2] stated "the largely negative findings with respect to genetic effects thus far is reassuring with regard to the magnitude of risk."

The remaining studies presented at the seminar concerned growth and developmental effects which are not relied to genetic effects. In addition to his genetic studies, Dr. Berman evaluated teratologic alterations while the majority of the studies indicated that microwave radiation had little or no consistent teratologic effect. He did note an increased incidence of craniopathies at 14 mW/cm^2. While temperature measurements were not reported, it is known that 14 mW/cm^2 does produce a severe thermal load on mice.

The research on structural defects in darkling beetles presented by Dr. Pickard indicated that the development defects were not due to overall gross heating but did not rule out selective hot spots. Research by Dr. Pickard has continued under joint BRH-Navy support. In addition, the Navy has continued to sponsor research in this area at Naval Aerospace Medical Research Laboratory, Pensacola, where Dr. Pickard spent three months as a guest scientist conducting joint research with Navy investigators.

The death of zebra fish embryos at non-thermal intensity levels is still a matter of conjecture. Dr. Barnes at the conference suggested that "the death of the embryos was not related to the attainment of a critical temperature, as a result of the microwave exposure, and that some nonthermal damage mechanism was operating to kill the embryos."[3]

In contrast, the following is quoted from the last summary technical report received from the investigator, "we have observed a definite thermal threshold for death of the embryos for peak powers up to 6.4 kW (average power=1.73 w). We have observed no effects attributable to non-thermal effects."[4] It is known that Dr. Barnes is continuing research in this area and further reports from his group may help to clarify the present uncertainty.

The delays noted in the onset of cell division in slime molds has been sponsored by the Navy in support of Project Seafarer. The frequencies utilized were 75 Hertz unmodulated and 76 Hertz modulated fields. This work has recently been evaluated by the NAS committee reviewing the biological effects of ELF fields. Again, this is a cellular response and not a genetic defect. The NAS committee felt that the results may have been the result of investigator bias but agreed that even if valid the results were interesting but not of major biological significance. The Navy is still conducting studies in this area.

Dr. Heller and associates published a series of articles, beginning in 1959, purporting to show "athermal" effects from radiofrequency radiation exposure.[5][6][7] These experiments were summarized and presented to the BRH sponsored symposium at the Medical College of Virginia in June 1970.[8] It is of interest to note the critique of Dr. Heller's work, also presented at that meeting,[9] as well as earlier criticism by Kolant.[10] The exposures were made by placing samples between electrodes and passing high (1000–1500 V) voltage current from a 27 MHz generator through the material. Although claims were made for the nonthermal nature of this system, no temperature measurements were made, nor were the power levels stated.

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[1] Fourth Report on "Program for control of electromagnetic pollution of the environment: The assessment of biological hazards of non-ionizing electromagnetic radiation." Appendix D. OTP/ERMAC, June 1976.

[2] Ibid. p. D-39.

[3] Ibid. p. D-10.

[4] Barnes, F. S., et al. Final Report, AF Contract F41609-73-C-0012, December 1974.

[5] Heller, J. H. and A. A. Teixeira-Pinto. A new physical method of creating chromosomal aberrations. Nature. 183:905-906, 1959.

[6] Teixeira-Pinto, A. A., et al. The behavior of unicellular organisms in an electromagnetic field. Exp. Cell Rs. 20:548-564, 1960.

[7] Mickey, G. H. Electromagnetism and its effect on the organism. N.Y. State J. of Med. 63:1935-1942, 1963.

[8] Heller, J. H. In: Biological Effects and Health Complications of Microwave Radiation. S. Cleary (Ed.), p. 116, BRH/DBE 70-2, 1970.

The fruit fly study reported by Mickey[11] could hardly be described as "low level microwaves." No power values were given, no temperatures were taken, and voltage across a narrow gap up to 3000 volts could readily produce instantaneous peak temperatures. Other studies on the fruit fly, notably Brauer Zelby[12] have reported no effects from RF exposure unless thermal levels were achieved. Under ONR contract, Mickey later exposed hamster cells to 200 mW/cm^2 X-band radiation and found no effect. Follow-on studies reported some positive findings, but no publication other than a contract final report resulted.[13]

In summary, it is the scientific consensus that Dr. Heller's early studies showing chromosomal abnormalities probably are not valid findings. The findings could be the result from elevated temperatures. Another alternative is, because of the high voltages involved, ion stripping at the electrodes could have taken place, resulting in ionized radiation.

With many of the remaining studies, it is too early to really determine their validity since all of the reports given were still in progress.

RECOMMENDATIONS ON GUIDANCE FOR TECHNIC TO REDUCE UNNECESSARY EXPOSURE FROM X-RAY STUDIES IN FEDERAL HEALTH CARE FACILITIES

PREFACE

The Administrator of the Environmental Protection Agency formed an Interagency Working Group on July 5, 1974, to develop guidance to reduce unnecessary radiation exposures from the use of X-rays in the healing arts in Federal health care facilities. The consensus of this group was that it is desirable and possible in Federal facilities to reduce exposure from diagnostic uses of X-rays by: (1) eliminating clinically unproductive examinations, (2) assuring the use of optimal technic when examinations are performed, and (3) requiring appropriate equipment to be used. As a result of this consensus a Subcommittee on Technic of Exposure Prevention was formed to examine the use of equipment and technic to perform medical and dental X-ray examinations and to make recommendations for guidance to assure that disagnostic quality radiographs are produced with minimal patient exposure. The recommendations made herein are believed to be basic to assuring that these considerations are met in Federal health care facilities.

A Subcommittee on Prescription of Exposure to X-rays has examined considerations for eliminating clinically unproductive examinations. Its report, which was published in March 1976, and this report will form the basis for recommended Federal radiation guidance for the use of X-rays in Federal health care facilities. This Subcommittee recognizes that the body of knowledge on both radiation exposure and technic for performing X-ray examinations is rapidly changing and the recommendations will, of necessity, need periodic review and appropriate revision.

INTRODUCTION AND RECOMMENDATIONS

The fundamental objective of an x-ray examination is to obtain optimum diagnostic information with minimum patient exposure. The achievement of optimum diagnostic information with minimum exposure requires: (1) assurance that all equipment is functioning properly and calibrated as required; (2) operation of equipment is only by competent personnel; (3) the patient is appropriately prepared; and (4) technic factors which will minimize exposure are selected.

The Subcommittee on Technic of Exposure Prevention has considered each of the above areas to assure that good technic is employed in Federal health care facilities. The recommendations of this report address quality assurance, radiographic technic, operator qualifications, and exposure guidance. Because many details of good radiographic procedures depend on good judgment by qualified professionals, the recommended guidance is stated in the form of broad principles. Programs of the various Federal agencies continue to develop information and procedures that are expected to lead to optimal mechanisms of meeting these broad principles.

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[9] Michaelson, S. M. Biological effects of microwave exposure. p. 47, In: BRH/DBE 70–2, op. cit., 1970.

[10] Kalant, H. Can. Med. Assoc. J. 81:575, 1959.

[11] Mickey, G. H., op. cit.

[12] Brauer, G., & L. W. Zelby. Effects of electromagnetic fields on genetic phenomena. EPA R 800436. 1976.

[13] Mickey, G. H., J. H. Heller and E. Snyder. Non-thermal hazards of exposure to radiofrequency and microwave fields. Final report, ONR Contract N00014–69–C–0176, 1975.

Within this framework, the following recommendations are made for guidance on technic for performing medical and dental radiographic procedures in fixed Federal and government owned contractor-operated health care facilities:

1. An equipment quality assurance program containing equipment specifications, equipment calibration requirements, materials and equipment performance requirements, and preventive maintenance schedules should be established in all Federal health care facilities.
2. The highest-speed film and film-screen combinations, which are consistent with image quality requirements, should be used.
3. Radiographic films should be stored, handled, and processed in appropriately equipped rooms. Periodic quality control inspections should be made for each aspect of film storage, handling, and processing that may affect radiographic quality or patient exposure.
4. The performance of diagnostic x-ray examinations should be in accordance with a procedural program which details patient preparation, use of technic charts, and quality control checks of finished radiographs to minimize retakes.
5. Operation of diagnostic medical x-ray equipment should be by individuals having adequate knowledge of radiation principles. These individuals should be qualified by a combination of didactic training and experience identical to or equivalent to the requirements of programs approved by either the council on Medical Education of the American Medical Association or the American Registry of Clinical Radiography Technologists.
6. Individuals performing radiographic examinations should select optimal technic and provide patients optimal preparation, instruction, and positioning; proper collimation and shielding should be used to restrict the x-ray beam as much as practicable to the clinical area of interest.
7. Facility protocol concerning examinations of pregnant or potentially pregnant patients should assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are applied.
8. Appropriate area shielding should be used to limit gonadal exposure where such protection does not interfere with the objectives of the examination.
9. Exposures from routine diagnostic x-ray examinations should be periodically determined, the technic evaluated, and practicable measures undertaken to reduce exposures for those examinations which exceed the following Entrance Skin Exposure Guides (ESEG):

Examination (projection):	*milliroentgens*[1]
Chest (P/A)	30
Skull (lateral)	300
Abdomen (A/P)	750
Cervical spine (A/P)	250
Thoracic spine (A/P)	900
Full spine (A/P)	300
Lumbo-sacral spine (A/P)	1,000
Retrograde pyelogram (A/P)	900
Feet (D/P)	270
Dental (bitewing and periapical)	700

[1] Entrance skin exposure for a reference patient selected by the next program to have the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, adbomen/23 cm, and foot/8 cm.

10. Operation of diagnostic dental x-ray equipment should be by individuals having adequate knowledge of radiation protection principles. These individuals should be qualified by didactic training and experience programs consistent with the Guidelines for Dental Hygienist and Dental Assistant Training Programs Radiology adopted by the Oral Radiology Section of the American Association of Dental Schools.
11. Intra-oral radiography should be performed with open-ended, shielded, position-indicating devices with the x-ray beam as near the size of the image

receptor as practicable; other body tissues should be shielded from the direct beam and stray radiation.

12. The highest-speed film or image receptor of ANSI speed group rating of "D" or faster should be used for intra-oral radiograph consistent with image quality requirements.

QUALITY ASSURANCE PROGRAMS

The production of consistent and high quality radiographs concurrent with minimal patient exposure depends on two important factors: quality performance of equipment and materials and optimal performance of the operator. Because of the complex interrelationship of equipment, technic, and procedural factors, each of which could affect radiographic quality and exposure, a functional quality assurance program to monitor the significant elements is desirable. Such a program is important to provide the diagnostician with consistent quality radiographs regardless of which operator or x-ray generator is involved in performing the examinations. At the same time such a program could minimize patient exposure and the number of retake examinations with an anticipated reduction in materials, equipment, and personnel costs.

There is considerable recognition of the need for quality assurance programs in diagnostic radiology. A Subcommittee of the Food and Drug Administration's Medical Radiation Advisory Committee views the existing lack of quality assurance programs in hospitals and outpatient facilities as a major source of unnecessary patient exposure and radiographs of poor diagnostic quality [1].

The benefits of consistently high quality radiographs and increased production efficiency would in themselves seem to provide compelling support for implementation of quality assurance programs in Federal health care facilities. In addition, it appears that a substantial portion of costs associated with a quality assurance program could be justified by savings of resources such as film, processing chemicals, and labor. Meeting the objectives of quality assurance requires periodic monitoring of equipment performance and standards of procedure. The design and scope of quality assurance programs are expected to vary. The program should be consistent with the clinical specialty and available resources.

Equipment and materials

The quality performance of equipment and materials is determined by such factors as: (1) initial verification of equipment performance per specifications, (2) ongoing testing and calibrations of equipment, (3) periodic cleaning, adjustment, and preventive maintenance for equipment, and (4) verification of material performance. The level of emphasis of each will vary according to the needs of each Federal health care facility. Therefore, the details for implementing each of these factors should be established by the appropriate authority.

Quality assurance of equipment begins with assuring that upon completion of installation and calibration of newly purchased equipment, and prior to its clinical use, that it meets Federal regulations [3] and any additional performance requirements. Once equipment has been placed into service, periodic performance and preventive maintenance surveys should be conducted to provide prompt remedial action and continuing assurance of desired operation.

It is important to monitor such parameters as x-ray tube potential, tube current, timer, beam quality, filtration, and focal spot size, especially when equipment is calibrated or receives preventive maintenance [3, 4, 5]. Another factor which often affects the optimum use of x-ray equipment is the beam alignment and beam-limiting device.

Because of the importance of equipment and materials in producing high quality radiographs, it is recommended that:

An equipment quality assurance program containing equipment specifications, equipment calibration requirements, materials, and equipment performance requirements, and preventive maintenance schedules should be established in all Federal health care faciliies.

The quality of the finished radiograph depends upon the condition of the film prior to its use; thus, it is desirable to evaluate periodically the quality of unused film. Considerations of time, cost, and traumatized patients associated with repeat exams also suggests the need for a program to ensure adequate evaluation and handling of films [6, 7, 8]. All films should be handled and stored under carefully controlled light, temperature, humidity, and background radiation conditions so that fogging can be minimized [8, 9, 10]. Use of "safe lights" to minimize film fogging requires the selection of appropriate filters for the particular wave length sensitivities of the films. Dark rooms should be appropriately designed and operated to eliminate light leaks.

A periodic review of film and film-screen combinations used and their performance is suggested to assure optimal high quality radiography with minimum patient exposure. Image receptors should be as sensitive as is practicable consistent with the requirements of examinations since the use of faster speed receptors generally reduce patient exposure [11, 12, 13]. On the other hand, cursory acceptance of advanced speed films or screens should not occur at the expense of compromising necessary diagnostic information.

It is apparent that patient exposures can vary significantly just on the basis of film/screen considerations. Image receptor combinations recommended in the summary report of the First Image Receptor Conference on Film-Screen Combinations can be used as a current guide in this regard [14]. The image receptor combinations discussed in this report represent a recent consensus of an assembled group of radiology experts.

For most cases, the typically preferred receptors ranged from par-speed film/par-speed screen to par-speed film/hi-speed screen combinations. Recent studies have shown that some of the newer film/screen combinations can achieve a reduction in exposure for the majority of diagnostic x-ray examinations by factors of two to four without a reduction in quality of the image [15, 16]. Reductions in exposure can be achieved with certain technic factors by the use of rare earth intensifying screens together with suitable films which match the light emission characteristics of the screens. On this basis, it is recommended that:

The highest-speed film and film-screen combinations, which are consistent with image quality requirements, should be used.

The concurrent objectives of consistently high quality radiographs and minimized patient exposure also require quality film processing. Whether processing is accomplished manually or by machine, the quality of the equipment, materials, calibrations, housekeeping, and preventive maintenance are important.

Automatic processing machines can, with proper maintenance and monitoring, be used to obtain consistent high quality processing. Selection of processors should assure that the processing achieved provides an image commensurate with the level of resolution and consistency of the other components of the radiology system [7, 17, 18]. A preventive maintenance protocol for automatic processors is particularly imporant because of the many moving parts susceptible to failure. The scheduled cleaning and maintenance recommendations of the equipment manufacturers or an equivalent should be followed.

The concentration and replenishment of chemical solutions, proper functioning of temperature, process speed, and other controllers are significant considerations of film processing equipment. One method of assuring quality of film processing is to use control films periodically, especially upon the introduction of new preparations of processing chemicals. Sensitometric strip techniques have been shown to be of value in monitoring the quality of film processing [3, 19, 20]. On the basis of these considerations, it is recommended that:

Radiographic films should be stored, handled, and processed in appropriately equipped rooms; periodic quality control inspections should be made for each aspect of film storage, handling, and processing that may affect radiographic quality or patient exposure.

Operational procedures

Monitoring of operator performance is important to ensuring that high quality radiographs are produced with minimized patient exposure. Upon receipt of an examination request, the x-ray equipment operator determines a patient's measurements and, in accordance with facility protocol, selects the film-screen-grid combination, the kV, and the mAs. Some facilities have both single and three-phase x-ray generators and use several film-screen-grid combinations. In such situations, an up-to-date technic chart which gives optimum values for each generator is especially important. The chart can be particularly important for unusual situations and when the usual operator is not available.

Reduction of the number of radiographic retakes is generally agreed to be important in eliminating unnecessary exposure. Common causes for retakes are patient motion, errors in exposure, collimation, or positioning. Values of reported retake rates have ranged from approximately two to ten percent [21, 22, 23, 24, 25] Some variation in retake rates is reflective of the medical specialty and whether the x-ray facility is in a clinic, hospital, or teaching facility. Every reasonable effort should be made to eliminate retake examinations.

Unnecessary duplicate examinations result in costs and patient exposure that should be eliminated. Use of examinations on file is basic to this concern. This consideration has been addressed in a large-scale pilot project to automate scheduling and file room functions [26].

Monitoring by qualified technologists of the final processed radiograph for diagnostic quality before the diagnostician views it appears to be of value in identifying problem areas. Prompt monitoring provides for timely repeat examinations with minimum inconvenience and anxiety to the patient and provides notice of poor performance of equipment or operators [27]. The recording of information related to retakes (e.g., the examination, projection, reason, technologist, x-ray generator, etc.) can assist in determining patterns of retakes and in decreasing their frequency.

It is recommended that:

The performance of diagnostic x-ray examinations should be in accordance with a procedural program which details patient preparation, use of technic charts, and quality control checks of finished radiographs to minimize retakes.

EQUIPMENT OPERATOR PERFORMANCE

It is possible to obtain a range of radiographs considered diagnostically acceptable by most radiologists and have entrance skin exposure vary by a factor of six to ten because of the choice of the various technic factors [28, 29, 30]. Because of the importance of operators in minimizing exposure they ought to be cognizant of those technic interrelationships which accomplish minimized exposure. Each patient should have confidence that equipment operators: (1) are adequately trained to produce a diagnostic quality radiograph, (2) know how to produce the prescribed radiograph with the lowest possible exposure, and (3) periodically demonstrate continuing occupational competence.

Operator qualification

Available evidence indicates that x-ray technologists who are trained and credentialed (registered, licensed, or certified by a State or voluntary credentialing organization) more often produce radiographs with lower average patient exposures than nontrained or noncredentialed operators [29, 31]. Such results should not be unexpected since many noncredentialed operators have little or no formal training in anatomy, patient positioning, radiation protection practices. The analyses of Nationwide Evaluation of X-ray Trends (NEXT) program [32] data and recent proficiency test results indicate that inadequately trained operators are likely to expose patients and themselves unnecessarily [29, 33].

Personnel responsible for patient preparation and positioning, selection of technic factors, radiation protection measures, and film processing should be trained to produce quality radiographs. They should also be able to optimize various technic factors of the x-ray equipment to produce the radiograph at the lowest practicable patient exposure and to use optimal procedures in working with patients and ancillary equipment to reduce to a minimum the number of repeat examinations [11, 28, 34, 35]. Performance of x-ray examinations by untrained personnel does not appear justified except for unusual circumstances.

Operator competence is normally achieved through the successful completion of a professionally approved training program which provides both a didactic base and sufficient practical experience. Such competence should be developed in accordance with training programs identical to or equivalent to those approved by the Council on Medical Education of the American Medical Association or the American Registry of Clinical Radiography Technologists.

Even though both didactic and practical training are necessary, the primary criterion is for each operator to accomplish and maintain a capability to perform optimal examinations. The American Society of Radiologic Technologists has advocated such a criterion [36]. Continuing competence and professional growth should be encouraged with specific opportunities to further the person's knowledge and skills through attendance at workshops and institutes.

A policy should be established by the responsible authority which details: (1) who may operate diagnostic x-ray equipment and the supervision required, (2) the education-training and/or proficiency requirements for x-ray equipment operators, and (3) requirements for continuing education and demonstration of proficiency. This policy should be reviewed periodically and revised as appropriate. It is recommended that:

Operation of diagnostic medical x-ray equipment should be by individuals having adequate knowledge of radiation protection principles. These individuals should be qualified by a combination of didactic training and experience identical or equivalent to the requirements of programs approved by either the Council on Medical Education of the American Medical Association or the American Registry of Clinical Radiography Technologists.

Operator Responsibility

The responsibility of operators in performing x-ray examinations should be discharged through adherence to prescribed protocol. The operator should not perform any examination which has not been prescribed for an authorized person. In performing an examination, he should prepare the patient on the basis of the requesting prescription and facility protocol. Patients should be attired suitably with all objects removed that might cause artifacts and be positioned properly. They should also be instructed when to hold their breath and on the position required in each view to prevent blurring of the radiograph due to motion.

Collimation of the x-ray beam and shielding of body areas not being examined minimizes unnecessary exposure. Regardless of all other technic considerations, the useful beam should be confined to the clinical area of interest [12, 13, 37, 38]. The beam size should be generally limited to the image receptor size or smaller. The operator has a responsibility to use shielding where appropriate and practicable to further limit the exposure of body tissues [11, 27, 28, 39, 40]. Therefore, it is recommended that:

Individuals performing radiographic examinations should select optimal technic and provide patients optimal preparation, instruction, and positioning; proper collimation and shielding should be used to restrict the x-ray beam as much as practicable to the clinical area of interest.

Special effort should be made to protect the blood forming organs of children [38, 41, 42]. Particular care should be exercised when a fetus may be irradiated. The determination of whether a female patient may be pregnant should be considered by the referring clinician when the x-ray examination is prescribed. In addition, the procedure followed by an x-ray facility should ascertain that such a consideration has been made prior to exposing the patient so that additional precautions may be taken. Such a procedure would provide a mechanism for the diagnostician to consult the referring clinician before conducting the examination or to alter the examination. If the examination could result in exposure of the fetus, operators have a responsibility to use shielding to minimize such exposure. Therefore, it is recommended that:

Facility protocol concerning x-ray examinations of pregnant or potentially pregnant patients should assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are applied.

Minimization of the Genetically Significant Dose (GSD) has been a major goal of radiological protection for many years in order to provide protection for future generations. In an effort to reduce the GSD to the population, the U.S. Food and Drug Administration, in cooperation with its Medical Radiation Advisory Committee and the American College of Radiology, has developed a proposed guideline (21 CFR 1000, Subpart C) which recommends the use of gonadal protection for those procedures in which the gonads lie within or are in close proximity to the x-ray field and where their exclusion would not compromise the clinical objectives of the examination [43]. Specially designed shields for males were field tested during the course of developing the proposed guidelines and were found to be a desirable action for minimizing the GSD. This consideration is particularly important for those examinations which result in gonadal exposure of persons of reproductive potential due to the increasing use of x-rays in medical care [12, 13, 37, 38, 41]. On this basis, it is recommended that:

Appropriate area shielding should be used to limit gonadal exposure where such protection does not interfere with the objectives of the examination.

PATIENT EXPOSURE CONSIDERATIONS

Production of a radiograph results in two determinants: the qualitative evaluation by the diagnostician of the required diagnostic quality of the radiograph and the amount of radiation exposure required to produce it. Each radiograph is evaluated for acceptable quality by a technologist or the diagnostician. An explicit evaluation of exposure is not usually made for each radiograph, although a change in radiographic quality generally provides an indication of exposure variation. A periodic evaluation of exposures in accordance with appropriate guidelines for routine examinations would appear to provide a mechanism to indicate levels above which good technic was probably not used and appropriate actions are warranted to reduce such exposures.

The development of exposure guides necessitates consideration of those technic factors which most affect the exposure. Data from the Nationwide Evaluation of X-ray Trends (NEXT) were used for this purpose as detailed in Appendix A. The NEXT data probably provide a representative profile of the practice of diagnostic radiology in the United States at the present time. These data reflect the myriad of combinations of x-ray generator types; high, medium, and slow films and screens; film processing technic; high, medium, and low contrast requirements of the diagnostician; and a range of skills of equipment operators. Therefore, regardless of the specific details or combinations of all these factors, the frequency distributions of entrance skin exposures (ESE) derived from the NEXT data are assumed to be sufficiently representative of the complex system of diagnostician preference, operator technic, and x-ray equipment performance for the selected routine examinations.

The distributions of ESE from the NEXT data (Appendix A, Figures 1–12) are generally skewed to the high exposure side and at some point they begin to represent unnecessary exposure due to poor equipment or less than optimal technic factors. The choice of the point in the distribution where exposures become unnecessarily high is difficult since it is necessary to allow for a normal range of diagnostician preference and state-of-the-art variations in x-ray generating equipment, ancillary equipment, and technic factors. Careful consideration of these factors and the ESE data from the NEXT program suggests that exposures above the third quartile (i.e., those in the fourth quartile) probably represent unnecessary exposure. In order to determine whether exposures in the fourth quartile were unnecessary, the military services reviewed such surveys to determine whether adjustments in equipment and technic factors could be made to reduce the ESE below the fourth quartile without significantly affecting image quality. For these surveys, it was found that minor adjustments in technic could reasonably be made to reduce values of ESE below the fourth quartile.

There are several examples for the use of the third quartile as the level above which patient exposures could be considered excessive. In the consideration of the range of exposures utilized for chest examinations as represented by NEXT survey data, a Bureau of Radiological Health staff report noted that "exposures falling above the third quartile can be considered as overexposures to patients" [29]. The Illinois Division of Radiological Health, Department of Public Health, reasoned that if 75 percent of the existing facilities could obtain a clinically acceptable radiograph by exposing patients below that level, then the other 25 percent of facilities should be able to alter their technic to reduce unnecessarily high radiation exposure [44].

The decision that exposure guides should be at the third quartile of the NEXT data accommodates these considerations. It is important, however, to emphasize that good technic can be selected which will generally produce practicable levels of exposure well below these guides. For each type of x-ray examination there exists, within available technology, an optimal combination of type of x-ray generator, technic factors and ancillary equipment to produce a diagnostic radiograph at optimal exposure.

Hence, it is important to evaluate each system to determine what exposure is as low as reasonably achievable and to establish procedures that routinely assure that exposures are consistently near that exposure level. Such determination require an evaluation of the diagnostic requirements, generators, films, screens, technic factors, etc. of each facility. In certain instances, it may be reasonable to exceed the exposure guide for the purpose of specified diagnostic information. The decision to exceed a guide should be based on an evaluation that the need for additional diagnostic information justifies the exception.

It is emphasized that these proposed guides apply to exposures for routine or non-specialty examinations and their implementation could be done with a reasonable expenditure of resources without restricting the diagnostician's preference for image receptor combinations and radiographic technic. On the basis of these considerations it is recommended that:

Exposures from routine diagnostic x-ray examinations should be periodically determined, the technic evaluated, and practicable measures undertaken to reduce exposures for those examinations which exceed the following Entrance Skin Exposure Guides (ESEG):

Examination (projection)	*ESEG (milliroentgens)*[1]
Chest (P/A)	30
Skull (lateral)	300
Abdomen (A/P)	750
Cervical spine (A/P)	250
Thoracic spine (A/P)	900
Full spine (A/P)	300
Lumbo-sacral spine (A/P)	1,000
Retrograde pyelogram (A/P)	900
Feet (D/P)	270
Dental (bitewing and periapical)	700

[1] Entrance skin exposure for a reference patient selected by the NEXT program to have the following body part/thickness: head/15 cm, neck/13 cm, thorax/23 cm, abdomen/23 cm, and foot/8 cm.

DENTAL CONSIDERATIONS

The basic objective of the use of radiation in dentistry is to obtain the optimal diagnostic yield with the minimum of exposure to the patient, dental personnel and the public [45, 46]. Therefore, the previous considerations of quality assurance, operator competence, and minimized patient exposure have the same applicability to diagnostic dental radiology. The significant use of radiographic procedures in dentistry warrants addressing elements of recommended practice specifically related to this profession.

Equipment Operator Qualification

The operator should receive the appropriate education and training in the areas of anatomy, physics, technic principles of radiographic exposure, radiation protection, radiographic positioning, and film processing that are relevant to dental radiography.

All training programs designed to qualify a person to perform radiographic procedures in dentistry should satisfy the Guidelines for Dental Hygienist and Dental Assistants Training Programs in Dental Radiography adopted by the Oral Radiology Section of the American Association of Dental Schools. These guidelines were developed to assure the protection of the public and improve the diagnostic yield of dental radiographs. Primary objectives of the guidelines are that ". . . upon completion of a dental radiology training program the dental hygienist and dental assistant should be able to:

1. Express and practice radiological health measures that are required by legal and/or ethical considerations;
2. Describe and demonstrate competency in theoretical considerations underlying radiation hygiene and radiological practice;
3. Expose, process, evaluate for quality, mount and file radiographic projections usually involved in dental practice;
4. Produce films with density, definition, contrast and other attributes of sufficient diagnostic value to the dentist" [47].

Therefore, it is recommended that:

"Operation of diagnostic dental x-ray equipment should be by individuals having adequate knowledge of radiation protection principles. These individuals should be qualified by didactic training and experience programs consistent with the Guidelines for Dental Hygienist and Dental Assistant Training Programs in Dental Radiology adopted by the Oral Radiology Section of the American Association of Dental Schools."

Technic

Technic is as important for producing quality dental radiographs as it is in general medical diagnostic radiology. Important aspects of dental technic for reducing patient exposure are the accurate positioning and the use of the smallest practicable X-ray beam to the clinical area of interest. Collimation for dental

X-ray systems to limit the beam should be in accordance with the beam diameter at skin entrance requirement of the Federal Diagnostic X-ray Equipment Performance Standards [21 CFR 1020.31(f)]. Significant advances in exposure reduction have been shown by the use of open-ended, shielded, position-indicating devices (PID) and a number of voluntary standard-setting organizations have recommended their use [45, 48, 49, 50]. In 1968, the Council on Dental Research of the American Dental Association (ADA) developed a set of recommendations which includes the use of open-ended shielded cones [51]. The Department of Health, Education, and Welfare has also recommended that dental practitioners should be encouraged through increased educational and training activities to adopt the paralle'ing, long-cone technic which uses the long open-ended shielded PID [52]. Regardless of other technic considerations, the useful beam should be limited insofar as practicable to the clinical area of interest through the use of definitive beam collimation and body shields. Therefore, it is recommended that:

"Intra-oral radiography should be performed with open-ended, shielded, position-indicating devices with the X-ray beam as near the size of the image receptor as practicable; other body tissues should be shielded from the direct beam and stray radiation."

In addition to the essential considerations of collimation, the general recommendation to use the fastest speed image receptor consistent with diagnostic requirements is again most important and appropriate. In 1968 the Council on Dental Research (ADA) recommended that dental clinics ". . . use the fastest speed film available" and that they ". . . request film of ANSI group rating of 'D' or faster" [51, 52]. On the basis of this finding and the resultant patient exposure reduction with adequate film quality, it is recommended that:

"The highest-speed film or image receptor of ANSI speed group rating of 'D' or faster should be used for intra-oral radiography consistent with image quality requirements."

It is recognized that the technic and technology of dental radiography are continually evolving and that new methodologies will be refined to provide practicable alternatives to current ones. The desirability of limiting the X-ray beam size to that of the image receptor has been accomplished only recently, for example, by rectangular collimation technic [53, 54, 55, 56]. Another approach which involves placing a new focused radiation source within the mouth to reduce patient exposure is being investigated at the National Institute of Dental Research [57]. Therefore, recommendations for dental radiography will, of necessity, need periodic review and appropriate revision.

APPENDIX A

The purpose of this Appendix is to present the data considered in developing exposure guidelines. The exposure data were obtained from the Nationwide Evaluation of X-ray Trends (NEXT), a program of the Conference of Radiation Control Program Directors [32].

The NEXT surveys provide the most recent data on radiation exposures and the corresponding technic factors used for selected radiographic examinations. Table 1 contains a list of the radiographic projections currently being surveyed in the NEXT program and the number of surveys conducted by the 37 participating States (labeled "all states") for the period July 1, 1973 through June 30, 1975 and the military services (labeled "Federal") from July 1973 through December 1975. The number of "Federal" surveys is quite limited when compared to "all-states" surveys, but both groups of surveys exhibit similar technic factors and exposure value summary statistics as shown in Tables 2, 3, and 4. For this reason, the larger statistical base provided by the "all-states" survey data were used as representative of patient exposure from X-ray examinations in Federal facilities.

The summary data in Tables 2, 3, and 4 do not demonstrate a consistent statistically-firm pattern for these factors. The frequency distributions of entrance skin exposures (ESE) derived from the "all-states" NEXT data for each examination/projection are shown in Figures 1 through 12. The distributions of these data are generally skewed to the high exposure side probably because of the use of either faulty X-ray generators or less optimal technic.

TABLE 1.—TYPE AND NUMBER OF NATIONWIDE EVALUATION OF X-RAY TRENDS (NEXT) RADIOGRAPHIC EXAMINATION SURVEYS

["All-States" July 1, 1973 to June 30, 1975 and "Federal" July 1, 1973 to Dec. 31, 1975]

Examination (projection)	Number of surveys	
	"All-States"	"Federal"
Chest (P/A)	1, 670	281
Skull (lat)	136	49
Abdomen (A/P)	564	135
Retrograde pyelogram (A/P)	122	20
Thoracic spine (A/P)	51	13
Cervical spine (A/P)	223	18
Lumbo-sacral spine (A/P)	695	97
Full spine (A/P)	47	3
Feet (D/P)	66	13
Bitewing dental	1, 752	138
Periapical dental	1, 055	115
Cephalometric dental	35	0

TABLE 2.—SUMMARY OF kVp FACTORS FOR NEXT SURVEYS

Type of examination	"All-States" surveys				"Federal" surveys			
	Number of surveys	kVp values			Number of surveys	kVp values		
		Mean	Low	High		Mean	Low	High
Chest (P/A)	[1] 1, 667	80	40	150	281	83	40	140
Skull (lateral)	136	72	48	94	49	73	58	92
Abdomen (A/P)	564	78	45	125	135	83	58	110
Retrograde pyelogram	122	77	55	106	20	72	58	82
Thoracic spine (A/P)	51	75	57	90	13	80	68	92
Cervical spine (A/P)	223	69	40	100	18	71	60	80
Lumbo-sacral spine (A/P)	695	77	55	106	97	79	62	100
Full spine (A/P)	47	79	64	96	3	76	72	80
Feet (D/P)	[1] 59	61	45	90	13	58	50	72
Dental (bitewing)	[1] 1, 750	71	40	110	138	84	60	100
Dental (periapical)	[1] 1, 054	71	40	110	115	83	43	100
Dental (cephalometric)	35	81	60	98	0	0	0	0

[1] The number of surveys differs from number of surveys given in table 1, due to omission of kVp entry in survey data.

TABLE 3.—SUMMARY OF mAs FACTORS FOR NEXT SURVEYS

Type of examination	"All-States" surveys				"Federal" surveys			
	Number of surveys	mAs values			Number of surveys	mAs values		
		Mean	Low	High		Mean	Low	High
Chest (P/A)	1, 670	12	2	100	281	12	1	100
Skull (lateral)	136	50	5	150	49	60	25	150
Abdomen (A/P)	564	85	2	300	135	87	2	200
Retrograde pyelograms	122	91	6	300	20	122	20	240
Thoracic spine (A/P)	51	82	12	200	13	91	30	160
Cervical spine (A/P)	223	48	2	200	18	33	20	60
Lumbo-sacral spine (A/P)	695	112	15	450	97	100	25	200
Full spine (A/P)	47	173	20	400	3	97	90	100
Feet (D/P)	66	18	1	80	13	66	2	150
Dental (bitewing)	1, 752	7	1	54	138	6	1	30
Dental (periapical)	1, 055	7	1	75	115	7	1	105
Dental (cephalometric)	35	18	3	60	0	0	0	0

TABLE 4.—SUMMARY OF ESE FACTORS FOR NEXT SURVEYS

Type of examination	"All-States" surveys				"Federal" surveys			
	Number of surveys	ESE values[1]			Number of surveys	ESE values[1]		
		Mean	Low	High		Mean	Low	High
Chest (P/A)	1, 670	24	2	266	281	33	3	369
Skull (lateral)	136	291	28	2, 730	49	337	39	2, 821
Abdomen (A/P)	564	601	22	2, 222	135	659	4	2, 471
Retrograde pyelogram	122	673	78	2, 200	20	558	62	1, 131
Thoracic spine (A/P)	51	646	60	1, 737	13	746	57	, 1572
Cervical spine (A/P)	223	206	13	1, 099	18	144	32	319
Lumbo-sacral spine (A/P)	695	787	41	5, 372	97	777	40	5, 544
Full spine (A/P)	46	275	70	1, 417	3	495	331	653
Feet (D/P)	66	275	28	2, 676	13	128	2	470
Dental (bitewing)	1, 752	579	62	6, 771	138	354	15	2, 258
Dental (periapical)	1, 055	588	51	7, 559	155	330	15	2, 345
Dental (cephalometric)	35	44	7	138	0	0	0	0

[1] Entrance skin exposure (ESE) in milliroentgens.

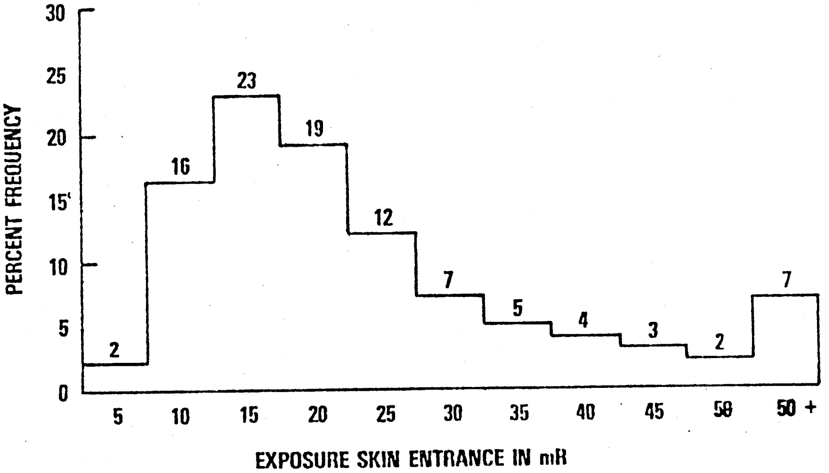

FIGURE 1.—Chest (P/A) 1,670 surveys.

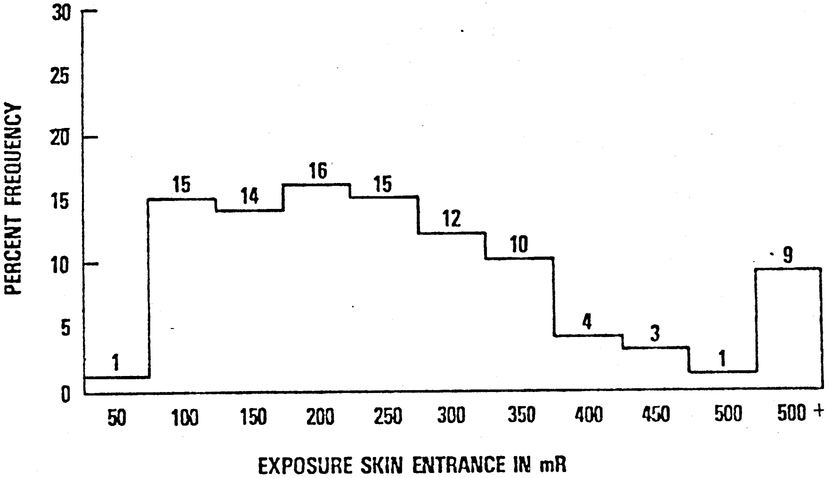

FIGURE 2.—Skull (Lat.) 136 surveys.

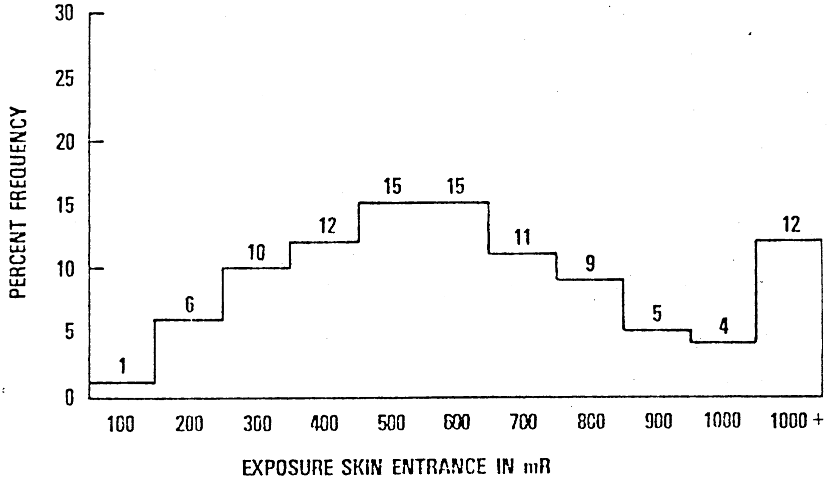

FIGURE 3.—Abdomen (A/P) 564 surveys.

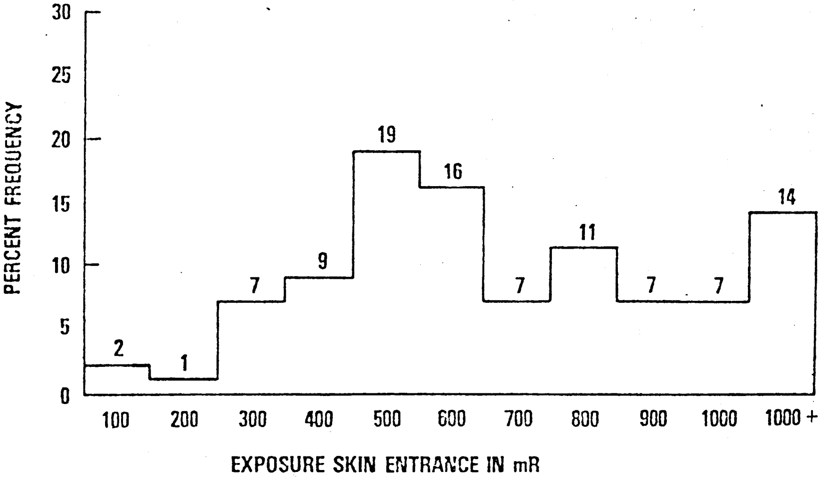

FIGURE 4.—Retrograde pyelogram 122 surveys.

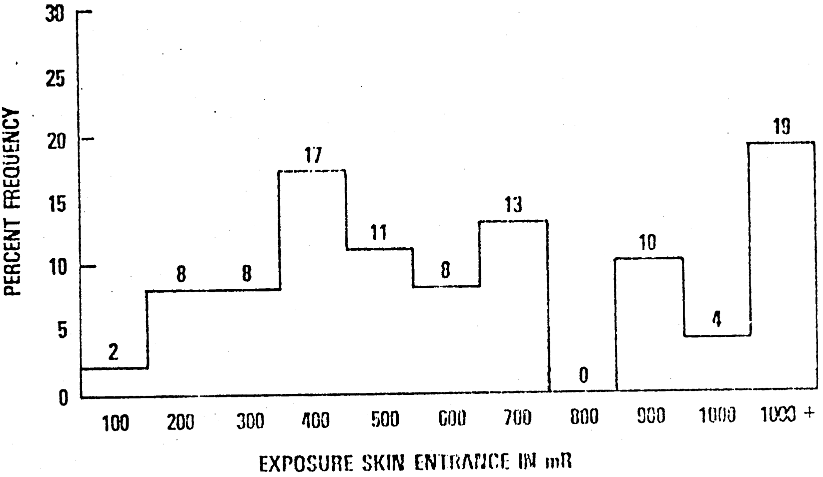

FIGURE 5.—Thoracic spine (A/P) 51 surveys.

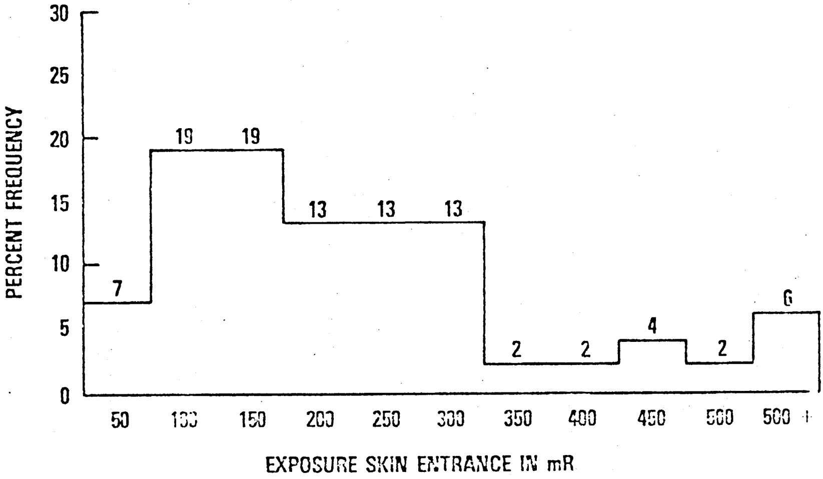

FIGURE 6.—Cervical spine (A/P) 228 surveys.

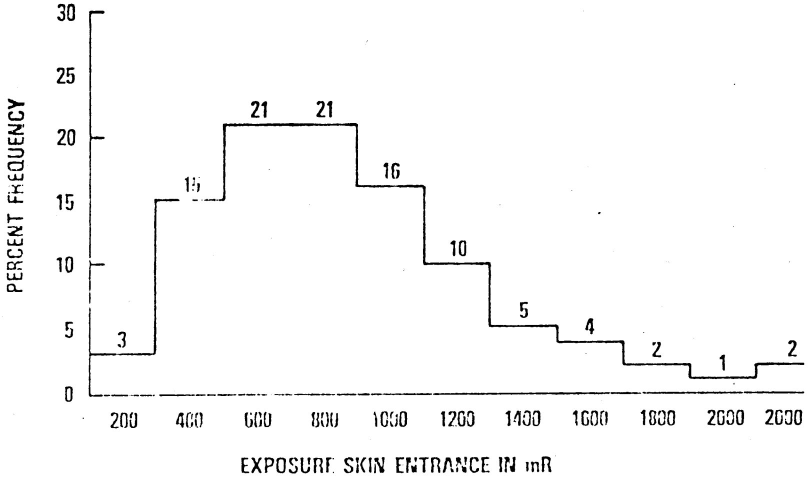

FIGURE 7.—Lumbo-sacral spine (A/P) 695 surveys.

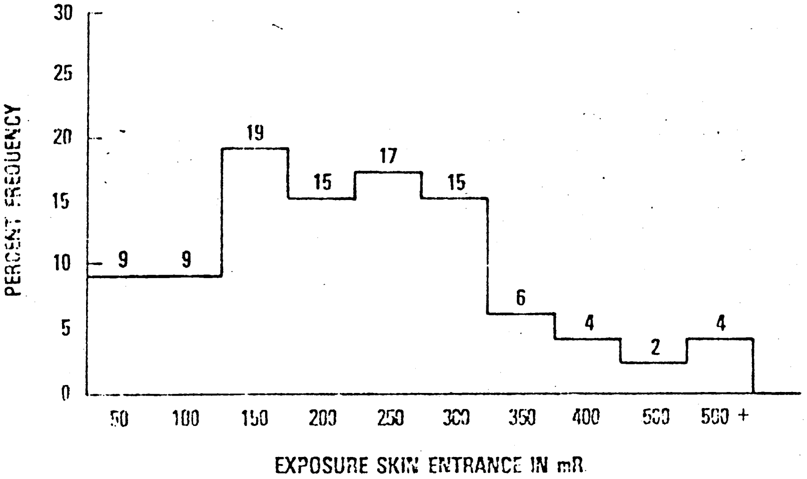

FIGURE 8.—Full spine (A/P) 47 surveys.

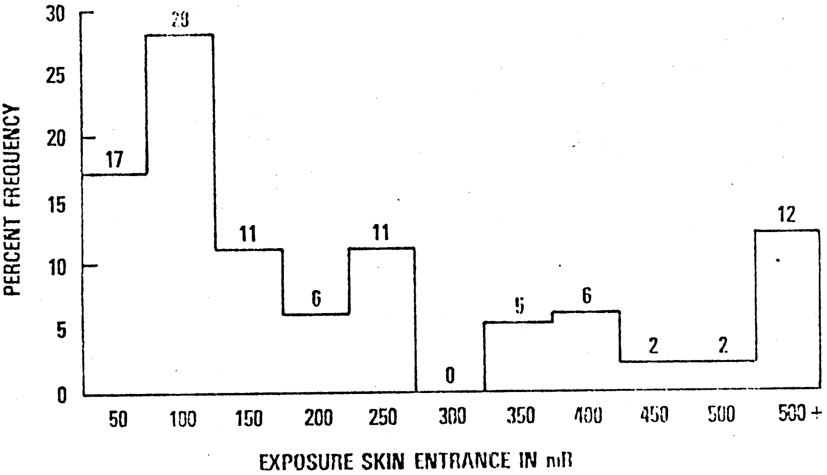

FIGURE 9.—Foot weight bearing (D/P) 66 surveys.

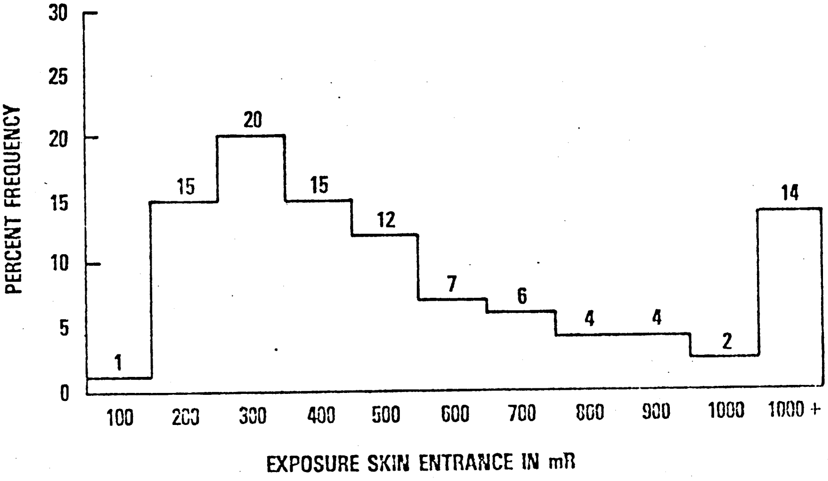

FIGURE 10.—Dental bitewing posterior 1,752 surveys.

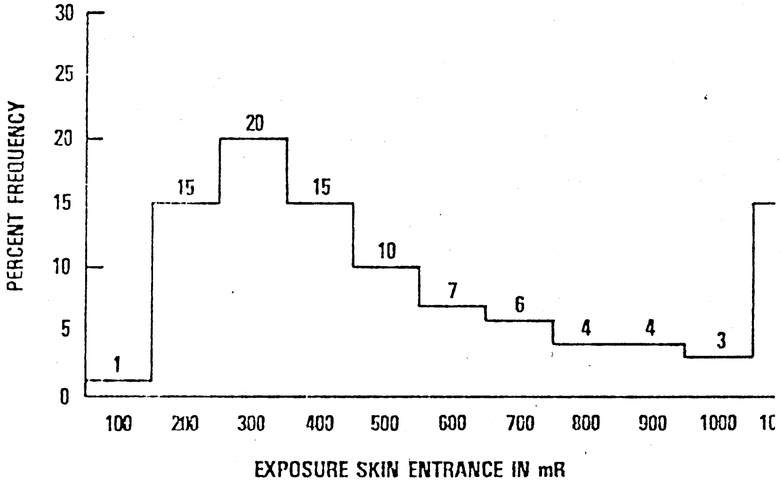

FIGURE 11.—Dental periapical 1,055 surveys.

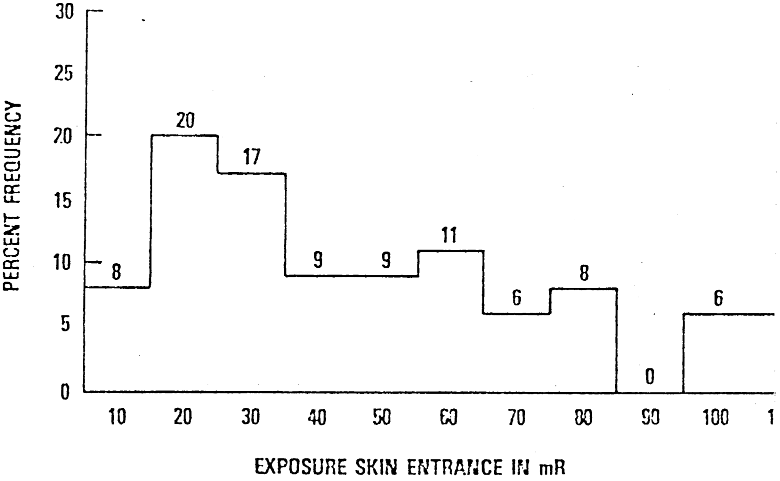

FIGURE 12.—Dental cephalometric (lat.) 35 surveys.

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MEMBERS

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CONSULTANTS

Otha Linton, M.S.J.; Director of Governmental Relations, American College of Radiology.

William Properzio, Ph.D.; Bureau of Radiological Health, U.S. Food and Drug Administration.

Captain AUSTIN. Shall we go ahead?

Senator FORD. Yes, sir. Go ahead.

Captain AUSTIN. Major Larsen?

Major LARSEN. Good morning, Mr. Chairman.

I appreciate this opportunity to testify to this committee. By way of introduction, I would like to say I am a physician serving as a major in the Medical Corps at the Department of Microwave Research, Walter Reed Army Institute of Research, which is a component of the Army Medical Department, Medical Research and Development Command.

I would like to begin my testimony and key it to the visual part of the presentation, if you please.

Figure 1 in the graphical components is a histogram showing Army spectrum utilization. By this I mean the total number of Army emitters is displayed as a function of the frequency in which they operate.

This graph illustrates the necessity for frequency-dependent research, if, for nothing else, the fact that the equipment follows certain frequency characteristics.

You will notice the vast majority of emitters is in the VHF band. This is used primarily for tactical communications. The band that is indicated as military band L is blackened in. The reason for this is because of the fact that this is a prominent radar band which is used in high-powered systems most often for satellite communications and air defense.

The second page gives the actual definitions of these bands in terms of frequencies just for the purposes of the record.

If I could direct your attention now, sir, to figure 3. This is a map of the United States showing the location of high-powered Army emitters in the L band. In this case, high-powered means total radiated power over 1 kilowatt.

Each one of these blocks indicates a radar site. There are many radars within each of these blocks, but it is apparent from this distribution that the majority of these radars are located in New Mexico, along the gulf coast, and a few along the mid-Atlantic States.

Figure 4 is a numerical description of these emitters in terms of the actual numbers of radars in L band at each one of these sites. You can see New Mexico has roughly 100 of them. The average number of radars per site is somewhere in the neighborhood of 15 to 20. The total number of these radars is around 200.

In order to assess the physiological-medical performance of these emitters, we have to consider the basic determinants of microwave bioeffects. This is the subject of figure 5.

There are two broad categories: the characteristics of the radiation and the characteristics of the biosystem. The characteristics of the radiation which we have to consider are things such as power, duration of exposure, frequency of radiation, modulation parameters (whether or not the radiation is pulsed, et cetera), and the geometry of the radiation in terms of focusing antennas.

The characteristics of the biosystems that are of importance include geometry (the way in which the system is oriented toward the field), how much energy is captured or transferred from the field into the biosystem, what sorts of microwave fields are induced as a result of being exposed to these fields, what are the temperature elevations, what organs, tissues, and cells and even molecules are involved. These determine the biosystem's response to incident radiation.

Figure 6 is a graphical illustration of the importance of frequency. This is one of the main themes in our testimony this morning. Frequency has to be considered over a very wide range, not just because of the fact that Army systems use a wide range of frequencies, but because of the fact that the potential for hazards covers a very wide range of frequencies.

This first figure illustrates the lowest frequency that we might want to consider. This is the frequency that corresponds to an electromagnetic wave that would best couple into the length, the total body length, of a person.

This illustrates a figure of a man whose height is roughly half the wavelength of the electromagnetic wave propagating nearby. Under these circumstances, energy transfer into the total man is optimized.

There are other frequencies where energy transfer is optimized for smaller targets. Figure 7 illustrates energy capture in the head. In this case, the frequency of the radiation is higher and the physical geometry of the target is smaller. And once again, conditions for optimal energy transfer into the head are different than those into the whole body, and have to be separately considered.

Going down in scale still further, the next illustration shows a top or vertex view of the head with an electromagnetic wave coupling into the eye. In this case the frequency which couples optimally into the eye is still higher and different than that which coupled into the whole body or the whole head.

The last level of analysis, in a sense, is shown in the next figure. It is microwave energy absorption by a single figure. It is microwave energy absorption by a single molecule. In this case, the molecule is ammonia, a molecule which is involved in proteins.

At a specific microwave frequency, the nitrogen atom in this molecule oscillates between the two positions shown in this graph. It extracts energy from the field at this single specific frequency. It is a very narrow band of phenomena.

With that introduction, in terms of what frequencies the Army has to employ and the possible frequencies that we have to consider from a medical point of view, what management strategy would we employ to pursue these questions?

The first element in the management strategy has to be the identification of effects. This immediately raises the question of whether they are due to continuous or pulsed radiation. What was the frequency employed? What was the power employed, et cetera?

These are important questions, not only because of spectrum utilization by Army systems, but also because of the necessity to define the limits of the effect.

The second element in the management strategy is to examine biophysical mechanisms. We believe that this is important because it enhances predictive value. In other words, we think that it is important that the microwave research program be sufficiently broad-based that we can provide prompt response to novel spectrum utilization that might be employed by adversary forces in the context of electronic warfare and electronic counter measures.

These are areas in modern warfare that are obviously not under the control of our own forces. Our program, in order to insure the health and safety of our personnel, should be able to respond in a proper manner to a threat of this sort.

As a result, we feel that it is necessary to analyze bioeffects at all levels of biosystem organization, as we said, from the simple length of the man to the size of his head, to his eyes, to the molecules themselves, and so forth.

The last step is to determine the medical hazard represented. This is largely based upon what organs and tissues are involved and what are the functional implications.

The microwave research program which is the result of this management strategy, has divided our laboratory effort into roughly five blocks. These five blocks are energy distribution and measurement, biophysical actions of microwaves, bioeffects of pulsed radiation (this is separated out as an individual element in the research program because of the fact that we believe this is a very important form of modulation); fourth, behavioral and other studies—"other" in this case meaning the central nervous system, cardiovascular system, and so forth; and fifth, the extramural program.

In the operation of this program, which dates from about 1975, we have accomplished a number of things, and we have identified areas for future research. These are the subject of the last two figures, 12 and 13, in the packet.

The first program accomplishment is the establishment of a rational management strategy for intramural as well as extramural research to determine potential microwave hazards.

Second, the program has developed methods for the measurement of tissue microwave properties. This research is being continued at the present time. We see many applications for it to help understand what happens to a responding, adaptive organism when it is exposed to microwave radiations.

This is quite different than, as Dr. Pollack said, heating meat in an oven.

Third, methods have been developed for the precise continuous measurement of temperature changes in the organs of the exposed subject animals. These temperature measurements are made while the fields are on and represent small regions of tissues with good accuracy.

Fourth, we have established the feasibility of nonsurgical methods for the measurement of microwave energy deposited in targets. We have not yet done this in living systems. Presumably, that will happen with animals sometime within the next couple of years.

This method of analysis is based upon computer analysis of fields going into and coming out of the target being exposed.

Fifth, microwaves have been demonstrated to have effects on basic biological processes. This includes things such as cell growth rate, cellular rates of metabolism, and so forth.

Point No. 6, unique hazards of exposure to pulsed microwave radiation, as compared to continuous exposure, have been reported. The further exploration of pulsed microwave effects is a major part of our program.

Seventh, behavioral effects of microwave exposure have been identified.

Eighth, the importance of antenna-like properties of animals and their organs has been demonstrated. This again emphasizes the importance of frequency specificity on microwave effects.

Ninth, no unique association has been found between occupational microwave exposure and cataract formation. This was the conclusion of a study directed by the Army Surgeon General.

It involved Walter Reed General Hospital and the U.S. Army Environmental Hygiene Agency.

Last, we would like to direct your attention to the emerging technology of potentially beneficial diagnostic and scientific medical applications of microwaves.

That concludes my presentation.

[The statement follows:]

STATEMENT OF MAJ. LAWRENCE EDWIN LARSEN, M.D., MEDICAL CORPS, ASSOCIATE CHIEF, MEDICAL BIOPHYSICS, DEPARTMENT OF MICROWAVE RESEARCH, WALTER REED ARMY INSTITUTE OF RESEARCH, U.S. ARMY MEDICAL RESEARCH & DEVELOPMENT COMMAND

INTRODUCTION

I am Dr. Lawrence Edwin Larsen. I graduated the University of Colorado School of Medicine in 1968. I had two years of post-doctoral training at UCLA in biomathematics and neurophysiology. I am a major in the Medical Corps of the United States Army and the Associate Chief for Medical Biophysics of the Department of Microwave Research at Walter Reed Army Institute of Research (WRAIR). I have been professionally concerned with the bioeffects of microwave radiation since 1970. Except for an 18 month period when I accepted a faculty position at the Baylor College of Medicine (Houston, Texas), I have been working in microwave research at Walter Reed.

GENERAL PERSPECTIVES

At present, microwave radiation represents a potential hazard to the health and safety of Army personnel as well as the general populace which may be exposed by Army microwave systems. The seriousness of this potential threat is unknown. The Army Medical Department is responsive to this situation and is vigorously pursuing a wide range of research programs designed to assess the health and safety implications of microwave radiation use at various frequencies and to provide a rational basis for regulatory actions.

Present program at WRAIR was initiated under the Medical Research & Development Command in 1971. The activities of this program are totally unclassified.

Programmatic direction is primarily concerned with establishing the existence of bioeffects and with elaboration of the biologic mechanisms which are the basis of these effects so that rational safety standards can be established. Changes as a result of microwave exposure have been identified in the brain, heart and eye to name only a few examples. Important details such as what frequency and how strong the radiation must be to create these effects as well as how the findings relate to the soldier in the modern Army remain the subject of present research. For example, it appears that microwave exposure will produce cataracts only at very high power levels.

The strategy of scientific management which underlies this effort is one aimed at understanding the basic biological actions of microwave radiation (with special cognizance of frequency dependent actions) at all levels of analysis. This orientation is intended to be sufficiently general and applied in order that the Army Medical Department may respond to the hazard analysis requirements of both the present and future Army uses of microwave radiation. Since systems developers must respond to the unpredictable utilization of microwave radiation by adversary forces, a research program limited to current systems will lack flexibility and predictive value. This management strategy is especially relevant to the burgeoning needs of electronic warfare and electronic countermeasures as important tactical requirements of the modern Army. In order to best serve the soldier in such an environment, we cannot wait until adversary forces deploy microwave systems of unexpected frequency characteristics. By that time it may be too late to develop the fundamental data base of bioeffects necessary to take protective measures.

Early findings in biomedical microwave research underlined the need for improved bioeffects instrumentation. Doubtful results came from equipment errors due to improper equipment performance in a microwave environment. In response to this problem, a basic instrumentation R & D program was initiated in 1972.

Additional basic biophysical research began in 1974 wherein the factors were identified which govern energy transfer into biological systems. This research revealed that biological objects such as man and laboratory animals extract energy from microwave fields in ways not unlike an antenna. This means that frequency and direction of the microwave radiation interact with the size and orientation of the biological target to determine the degree and nature of the bioeffect.

Recent work (1975 to the present) continues to explore the notion of frequency dependent bioeffects not only at a level of total energy capture by men and laboratory animals, but also at the level of body segment (e.g. head) and organ (e.g. occular) specific patterns of spatial energy distribution. This has important implications for understanding both potentially beneficial and potentially harmful effects of microwave radiation. Furthermore, frequency dependent studies have expanded to include the basic units of biology, cells and molecules. Understanding microwave actions at this level, the so called microscopic level, will allow valid prediction of hazards from modern Army microwave systems.

Before going further, it will be useful to clarify in general terms the importance of frequency. Army microwave systems use a number of specific microwave frequencies. Our research concentrates on the effects of those frequencies, but also considers other frequencies to establish the limits of the effects observed. Frequency sensitive effects in biosystems are expressed over ranges that cover factors from two to ten. Bioeffects identified at some frequency are not likely to be different from effects at frequencies only 10 percent higher or lower. However, it is likely that effects at some frequency will be different than those at twice or one half that frequency. Safety standards in the future may have to be framed in terms of specific frequency ranges. It is also important to be aware of the fact that operational systems presently in the inventory cover a very wide range frequency. What is not so immediately obvious is the fact that most operational systems do not use a single frequency radiator. Many systems use multifrequencies. In addition, most systems use some form of modulation or pulsing of the carrier wave. Pulsing is especially important since by its very nature it is broad-band due to the fact that radiated energy quickly moves from zero power to high power. Another commonly used radar signal is the "chirp," whereby frequency is systematically altered during some segment of time. In addition, secure communication systems make use of intentional spectrum spreading techniques. This results in a complex picture of special utilization which must be considered in the design of a biomedical microwave research effort.

For predictive value a hazards oriented microwave research program must quantify the basic parameters of electromagnetic field induction in biosystems due to microwave exposure. This requires measurement of microwave energy distribution within biosystems and measurement of certain immediate consequences of field induction such as temperature elevation in the exposed organ or tissue. The problem can be segmented into three steps: (1) The first thing that must happen to produce an effect is field induction in the biosystem. (2) Subsequently, microwave currents will flow in various ways in the biosystem dependinig on the frequency of the microwave radiation and electromagnetic properties of the biosystem's interior. Functional implications depend on what organs are involved (e.g. microwave energy deposited in a brain has different consequences than microwave energy deposited in a limb). More precise analysis depends upon the details of the situation (frequency, cell component, current densities, etc.) at the microscopic level. (3) Medical evaluation of the effects on the whole organism can only be done after steps 1 and 2 are precisely defined. The approach outlined above obviates the need for human experimentation. Successful application of this approach will provide some measure of freedom from the problem of species specific experimental effects.

A microwave research program should also include epidemiological studies. Unfortunately, our work in this area is made significantly more difficult since the methods of measuring exposure are faulty and the scientific basis of the specific medical consequences of exposure is in its infancy. The first question an epidemiological study must answer is what to study. One example where that question could be answered is cataract formation. The Army Surgeon General organized a retrospective occular study in radar operators and technicians conducted jointly by Walter Reed Army Medical Center, Walter Reed Army Institute of Research and U.S. Army Environmental Hygiene Agency (USAEHA). Exposure history for the subjects was estimated by occupational criteria. The conclusion of the authors was that no unique association could be identified between occupational microwave exposure and cataract formation. Additional epidemiological studies are being attempted but all suffer from the lack of technology to assess microwave bioexposure and microwave bioeffects.

To assure the relevance of our research program an inventory of U.S. Army microwave utilization is necessary. Army microwave systems are carefully catalogued and analyzed by the DOD clearing house on spectral utilization—the Electromagnetic Compatibility Analysis Center (ECAC). The Walter Reed microwave research program closely coordinates with ECAC in order to be appraised of radar systems which are under development or presently deployed. These systems are characterized by total radiated power, power density, operating frequency, modulation parameters and the like. This information in conjunction with on site surveys by USAEHA (itself a major contributor to the ECAC data base) is our best estimate of threat from planned, developmental, and operational Army systems which use the electromagnetic spectrum.

In summary, the management strategy of the microwave research program is designed to address the safety hazards of U.S. Army microwave systems in terms of their effects on man and his critical biologic and psychologic functioning. The program is intended to permit assessment and prediction for application to operational systems design, and to prepare for novel spectral utilization which may occur in modern warfare due to exposure from various combinations of emitters.

PRESENT AND PLANNED MICROWAVE RESEARCH PROGRAM

In terms of major blocks of laboratory effort, approximately one third of the total is dedicated to the dosimetric study of field coupling and macroscopic energy distribution in biosystems, one third is applied to the analysis of microwave effect mechanisms at the microscopic (cellular and molecular) level, and one third is directed toward the investigation of physiological and behavioral implications at the organ and organism level. The special role of pulsed radiation runs throughout these program segments.

Energy distribution and measurement

Energy distribution and measurement is a major segment of the Army program. It is also the number one priority in the Triservices microwave research plan. The rationale for this priority is expressed in the Triservices document as follows: "Meaningful interpretation of any biological response resulting from EMR (electromagnetic radiation) exposure requires detailed knowledge of the quantity and distribution of energy in the organ or bio-area being studied. The lack of such information in many current EMR bioeffects studies makes it extremely difficult if not impossible to extrapolate from the response measured in test specimens (mice, rats, dogs, monkeys) to the expected response in a person exposed to the same incident radiation field."

The Army microwave research program includes studies of frequency dependent energy absorbtion in physical models, in animals, and in organ specific studies. The physical models are scaled figurines of man. In these models, energy capture was found to be maximized when the long axis of the model was parallel to the direction of the electric field component of the electromagnetic field. Under free space exposure conditions, this maximum appears to occur when the frequency corresponds to a wavelength roughly twice the length of the long axis of the model. If the model was electrically grounded, it appeared twice as long and the frequency of maximum absorbtion was halved. In the case of the average height man (1.75 meters), these conditions correspond to 68 and 34 MHz, respectively.

These same sort of effects occur in body segments such as limbs, head, torso and so forth. Each of these have frequency dependent characteristics that determine energy absorbtion. Data of this sort may be used to predict the site of greatest risk for a given microwave frequency. Current research is verifying these predictions not only in physical models, but also in the laboratory rat and in special target organs such as the eye.

To further test the antenna-like properties of animals and physical models of man, studies were conducted with flat metallic plates located immediately behind the model. At the optimal combinaion of distance, direction and frequency, energy capture was enhanced by a factor of 4. Still larger enhancement factors were found with metallic plates shaped into 90° corners. Under optimal conditions an enhancement factor of 11 was measured. These studies simulate the effect of physical features in the environment which contribute to the risks associated with microwave exposure in operational situations.

Organ specific studies were conducted at WRAIR where intense microwave exposures were localized to the eye. It was found that repeated high level exposures were necessary to produce cataracts in experimental animals. The Army portion of a Triservices occular effects program measured temperature elevation in two sites within the eye of monkeys exposed to various frequencies of microwave radiation. The finding was that the location of greater heat production in the eye could be varied from a site just behind the lens (a susceptible site for possible cataract hazard) to a site just in front of the retina (a site with possible visual effects) by changing the frequency of incident radiation under controlled circumstances.

Another Army program is designed to study energy distribution in individual organs and tissues with noninvasive techniques. This is a longterm research program which has successfully completed its feasibility phase. This project has successfully imaged models under two layers of materials in water dominated environments. A physical model constructed to simulate two 1.5 mm blood vessels centered in a block of fat has been successfully scanned. If completely successful, non-invasive, three dimensional, mapping of microwave energy distribution in a living animal will be possible. This program provides a way of measuring microwave energy distribution within a subject without surgical implantation of probes. Since all microwave toxicity, therapeutic effects and diagnostic potentials depend upon field induction within the biosystem, this program provides a linkage between these major areas of research. Furthermore, this program will address hazards in terms of spatial distribution of microwave energy in critical areas depending on the frequency and form of the microwave radiation. An atlas of organ involvement for various frequencies of incident radiation is the ultimate goal. In addition, there is the distinct possibility that biomedical imagery of diagnostic importance can be obtained with this method. Microwave radiation measures critical aspects of healthy and diseased tissues and organs that are not visualized by X-ray.

The pattern of transmitted energy in time and space contains all the information necessary to create a three dimensional reconstruction of the spatial distribution of microwave energy in a biosystem. This can ultimately permit the empirical, non-invasive characterization of biosystems in terms of the spatial distribution of microwave energy induced by incident radiation.

Another effort on energy distribution and measurement is the microwave integrated circuit electrode development. This effort presently centers on the development of microwave transparent probes to be surgically implanted in the subject animal for temperature and electric field measurements during microwave exposure. All manner of microwave effects in biosystems must be characterized in terms of temperature elevation and induced electric fields. Earlier workers were forced to employ incremental before-and-after-type temperature measurements. Some previous bioeffects research has used instrumentation which made inaccurate measurements because the probe or instrument altered the microwave field thus compromising the measurements. Other instruments used in such research were too large in size or limited in accuracy for precise usage. The instruments developed at the WRAIR should solve many of these problems.

Safety standards which relate permissible exposure levels to heat production within the animal can only be established when temperature change is properly measured in the organ or animal. Future work will consist of the development of an implantable version of the temperature encoding electronics and a method of measuring temperature change in an unrestrained animal.

The microwave transparent temperature electrode will find many applications in the Walter Reed hazards research effort. Among these is the measurement of temperature elevation during exposure of the eye to microwave radiation. This will permit an estimate of cataract hazard potential for specific frequencies at lower levels of power than presently used. This probe will be a critical tool for investigating temperature changes in the brain. This is exceptionally important in the investigation of how microwaves affect the way an animal or man regulates body temperature.

Electric field measurement is also necessary. Although the microwave radiation from an antenna may be well specified. The quantitative capture of energy by specific target organs and tissue remains unspecified in the absence of electric field measurements.

The electric field probe is presently in the stage of feasibility study. Certain technologies will be borrowed from the temperature electrode. General program timing is intended to fill the need for measurement of internal energy distribution prior to the time when noninvasive measurements will be fully operational.

Biophysical actions of Microwaves

After microwave field induction is quantified, the next elements of a program are to determine the mechanisms of microwave interaction with biosystems and to assess the hazard potential. This program will permit characterization of microwave radiations in terms of their action on critical biologic processes. Microwave radiation has the potential of affecting forces that hold complex molecules in certain shapes. When molecules change their shape, their biologic activity is likely to change. For the molecular biologist the way molecular shapes relate to each other is the essence of life itself. All living organisms depend for their adaptive functioning and survival upon their capacity to recognize, produce and utilize molecules with highly specific structural characteristics. Microwave effects on these structural characteristics have the broadest possible implications for understanding the effects of microwave energy on any living organism, including man.

Several areas of development are involved. The first of these is the development and fabrication of a system for rapid measurement of properties of tissues which determine their response to microwave frequencies. Preliminary studies have confirmed the feasibility of such measurements. It appears to be practical to define the physical properties of biosystems which are responsible for the way in which microwave energy propagates through them. The ultimate goal is to relate power level, frequency, tissue properties and toxicity in order to predict the effects of microwave radiation at a specific frequency range.

A system to permit measurement of microwave properties in the living tissue of an animal is necessary. Microwave properties are available for many types of dead tissues. Rarely have data been obtained from living tissues. It is the data from living tissue that is relevant. Efforts directed at developing an appropriate electrode methodology for making measurements in living tissue are underway and current data point toward successful completion.

Cell membranes (rabbit red blood cells) have been subjected to multifrequency microwave analysis. It has been determined that microwaves are responsive to the operation of chemical transport systems resident in the living cell membrane. Disrupted cells do not have these properties. The method can also detect very small movements of ions and water across the cell membrane. As a technologic byproduct of this work, the actions of membrane active drugs (e.g. steroids and antibiotics) have been quantified with this method of microwave analysis.

The work previously described is just the beginning of a larger research program to assess the nature and functional consequences of microwave interaction at the cellular and molecular level. This sort of consequence has long been claimed by workers in Eastern Block Nations. If further work establishes this effect as an important one in intact animals then its implications for both microwave safety standard and possible biomedical applications will be profound.

Bioeffects of Pulsed radiation

All studies of pulsed radiation (except one behavioral study) are grouped into this section. The widespread us of pulsed microwave in radars demands a separate program for the exploration of effects peculiar to this form of energy delivery. Present knowledge in this subject begins with the fact that pulsed microwaves directed to a solid, non-living object cause that object to emit sounds. Furthermore, when microwave pulses are directed to the head of a human subject, the subject perceives sounds to emanate from within the skull. At the present time, we believe that this effect is the result of expansion within the inner ear. Less certain findings associated with pulsed exposure are alterations in the blood brain barrier and increased susceptibility to seizures. Alterations of the blood brain barrier permit chemicals that would normally be excluded to enter the brain from the circulation. Attempts to replicate Eastern Block results in animals susceptible to fits from other causes indicated that a transient effect was observed only with exposures many times higher than the safety standard. It must be emphasized that these last two effects are far less certain than the first two.

A necessary step in such a program is to characterize the physical expansion associated with a microwave induced pressure pulse. Theoretically, microwave energy delivered in a pulsed mode has a capacity to produce a physical distortion of tissue. This effect is uniquely associated with pulsed energy delivery and could not be obtained when a microwave is transmitted as a continuous wave. In order to characterize this phenomenon, it is necessary to construct an appropriate exposure system, then to expose tissue to pulsed microwave and measure the physical distortion in the tissue. Studies indicate that development of such an exposure system is feasible. Another step is to identify the biophysical consequences of such an expansion and to assess the functional significance of the phenomenon.

Further studies of pulse effects on the brain and its relationship to circulation are necessary in order to evaluate possible alterations in the blood brain barrier. This need prompted the WRAIR to convene a consulting group of senior civilian scientists to review existing work and to advise on future research. The panel advised that initial studies be done in simple membrane systems so that changes in the membrane induced by microwaves might be more easily measured and interpreted. In addition, they made other recommendations concerning the most effective ways to study this complex matter in intact animals. These recommendations are presently the subject of a joint Walter Reed Army Institute of Research/Naval Medical Research Institute protocol.

Behavioral and Other Studies

The central nervous system in general and behavior in particular are sensitive to microwave bioeffects. The WRAIR has considerable experience in behavioral studies of microwave radiation.

Early studies of a rat performing a simple task for food demonstrated that work stoppage resulted from exposure to microwave radiation. This effect was different for specific frequencies. At a given frequency, lower power levels required longer exposures to produce work stoppage. In no case did exposure at power levels lower than current safety standards produce a disruption in the animal's behavior. The frequency specificity of microwave effects on the organism was further confirmed with lethality studies, and in studies which measured the effect of microwaves on body temperature.

Behavioral studies are augmented by whole animal calorimetry for a measure of whole body energy absorption. In those systems where the "target organ" is the whole animal, i.e. where exact sites of action are either unknown or widely distributed, the one measure for the absorbed microwave energy is total absorbed energy. The objective is to measure absolute energy absorption in animal bodies which are free from metabolic heat production; and to obtain a quantitative measure of whole animal energy capture from microwave fields.

Behavior is used to assess an animal's response to microwave environments. It has been a valuable way to assess microwave effects at low power levels in the absence of reliable methods of measuring specific changes in body function in a microwave field. A special arrangment of containers (i.e. a shuttle box) was used to study the spatial preferences of animals. One compartment was exposed to pulsed microwaves while the other compartment was not. Frequency was chosen so that maximum energy transfer to the rat would occur but the average power was well below the safety standard. The animals will actively avoid exposure by migrating and remaining in the unirradiated compartment. In this study, the animal is acting as a biosensor, and is telling us that it finds the effects of pulsed microwaves at a specific frequency undesirable.

Another design which explores behavioral and motivational effects due to microwave exposure at or near the safety standard is conditioned aversion or microwave induced bait shyness. Bait shyness occurs if an animal feels sick after being exposed to a new event. Thereafter the animal will avoid whatever occurred at the same time as the new event. Bait shyness is produced if microwave exposure, the new event, is paired with the taste of saccharine water which the rat otherwise finds very desirable. After such an exposure the rat will not consume the previously desirable saccharine. Temperature elevations in the rat appear to be necessary to create this aversion. The conditioned aversion design is well known to be a sensitive behavioral system for noxious properties of radiation.

Behavioral studies may also examine the role of combined stress (temperature and humidity in the microwave exposure environment) by use of latency to convulsion in the laboratory rat. Combined stress reduces the animals' capacity to dissipate heat. This can be related to the animal's capacity to withstand heat loading during an acute, high level exposure to microwave. Elapsed time to the onset of a thermal seizure after beginning high power microwave exposure was used to measure vulnerability under various combinations of ambient temperature and relative humidity. A decrease in mean latency of 70 percent occurred with an increase in temperature-humidity index from the lowest value (58.6) to the highest (85.5). The microwave heating hazard is strongly influenced by the temperature and humidity of the environment in which microwave exposure takes place.

Extramural programs

Extramural users and contractors constitute a critical portion of the research program. One level of contract activity is that for technical support. This includes the following major items: (1) Westinghouse Electric Corporation

(Maryland) where microwave circuits were fabricated for the temperature electrode program; (2) Middlestadt Machine Co. (Maryland) where the microwave scanner used to measure energy deposition in models was manufactured; (3) American Electronic Laboratory (Connecticut) where specialized antennas were built; (4) Georgia Institute of Technology (Georgia) where microwave transmitters were built; (5) Mead Data Central (North Carolina) where the world microwave data base is maintained; and (6) Cober Electronics (Connecticut) where the WRAIR high power microwave transmitter was designed and built.

Other contracts are for research and collaboration with the intramural WRAIR program. These include the following: (1) University of Utah (O. Gandhi) where much of the antenna modeling of animals was significantly advanced; (2) Georgia Institute of Technology (A. Ecker) where tissue microwave parameter work was supported; (3) Medical College of Virginia (S. Cleary) where studies of blood chemistry changes after microwave exposure were supported; (4) Westinghouse Electric Corp. (Maryland) where transmission line development and electric field probe design were carried out; and (5) Sanford Research Institute (P. Polson) where chronic microwave exposure cage-cavities were developed.

Extramural users include: (1) American University (Dr. Varma) and George Washington University (Dr. Albert) carried out microwave exposure under Navy contract; (2) Armed forces Radiobiological Research Institute (G. Catravas, G. Oosta and others) carried out exposures for various experiments; (3) Environmental Protection Agency (D. Janes) uses WRAIR facilities for antenna calibration; (4) Bureau of Radiological Health (Mr. Swicord) uses WRAIR microwave research department facilities for computer analysis of tissue microwave properties; (5) WRAIR exposure facilities were used by the United States Air Force (J. Mitchell) for studies of the effect of microwave on electronic heart pace-maker malfunction.

To a large degree, these programs have been integrated into the main discussion because most are so closely connected to the internal program that continuity was best served by only a simple tabulation in this section.

TECHNOLOGY AND SCIENTIFIC BYPRODUCTS

Th multitude of suspected and demonstrated microwave interactions with biosystems suggests that this form of radiation has high biological relevance. This implies a complement to bioeffects research in terms of scientific and diagnostic applications for microwave radiation. One clear and present example from the Army microwave research program is the microwave chemical inactivator. This has proven to be a valuable tool in study of effect of stress or drugs upon the brain. (The Air Force program has also contributed to this development.)

Another example with profound implications for medical care is the advent of microwave based diagnostic systems. The prospect of biomedical imagery based on low level microwave radiation opens many possibilities for technology base development with implications beyond the DOD. Microwave based systems do address uniquely relevant attributes of living tissue at the molecular level (rather than an atomic level as is the case for X-ray based systems). Thus, many of the molecular specializations intimately associated with health and disease are potentially measurable by microwave based systems.

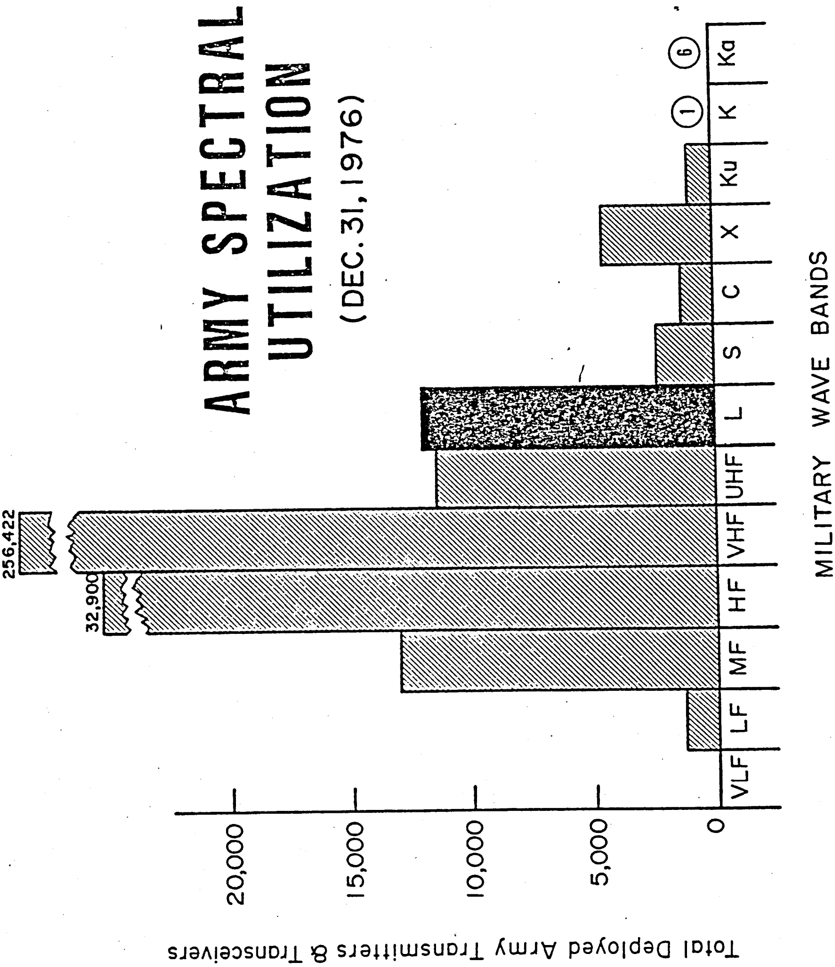
The physiological role of the cell membrane in the sustaining of specialized tissue environments is now subject to multifrequency microwave analysis to assess its functional status. Furthermore, the importance of microwave measurement for the assessment of tissue disease, drug actions and health may prove to be an extremely valuable tool for medical science.

This development into scientific and diagnostic applications is a direct result of Army support of multidisciplinary research program tuned to the needs of flexibility and prediction in microwave bioeffects research.

A word of caution is appropriate. An application of microwave diagnostic tools in man will require a great deal more work, most of it under sponsorship of institutions other than the Armed Forces. Further, the issues of hazards potential in the use of microwaves for diagnostic purposes will have to be resolved much more precisely before their beneficial potential can be realized.

SUMMARY OF PROGRAM ACCOMPLISHMENTS

1. A rational management strategy has been developed for intramural and extramural research to determine potential microwave hazards.
2. Methods for the measurement of tissue microwave properties have been established.
3. Methods have been developed for precise, continuous measurement of temperature changes in the organs of exposed subject animals.
4. The feasibility of non-surgical methods for the measurement of microwave energy deposition by complex computer analysis has been established and is undergoing further development.
5. Microwave effects on basic biological processes in animals have been demonstrated.
6. The unique hazards of exposure to pulsed microwave radiation, as compared to continuous microwave exposure of the same frequency and average power has been reported.
7. Behavioral effects of microwave exposure have been identified.
8. The importance of antenna-like properties of animals and their organs has been demonstrated. This results in frequency specificity of microwave bioeffects.
9. No unique association was found between occupational microwave exposure and cataract formation.
10. New potentially beneficial diagnostic and scientific medical applications of microwaves have been identified.


ARMY SPECTRAL UTILIZATION
(DEC. 31, 1976)
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20,000
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LF
MF
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VHF
UHF
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Ku
K
Ka
①
⑥
MILITARY WAVE BANDS
Total Deployed Army Transmitters & Transceivers

FIGURE 1

FIGURE 2.—*Military Band Designations*

VLF	3–30 KHz	S	2–4 GHz
LF	30–300 KHz	C	4–8 GHz
MF	300–3000 KHz	X	8–12. 5 GHz
HF	3–30 MHz	Ku	12. 5–18 GHz
VHF	30–300 MHz	K	18–26. 5 GHz
UHF	300–1000 MHz	Ka	26. 5–40 GHz
L	1–2 GHz		

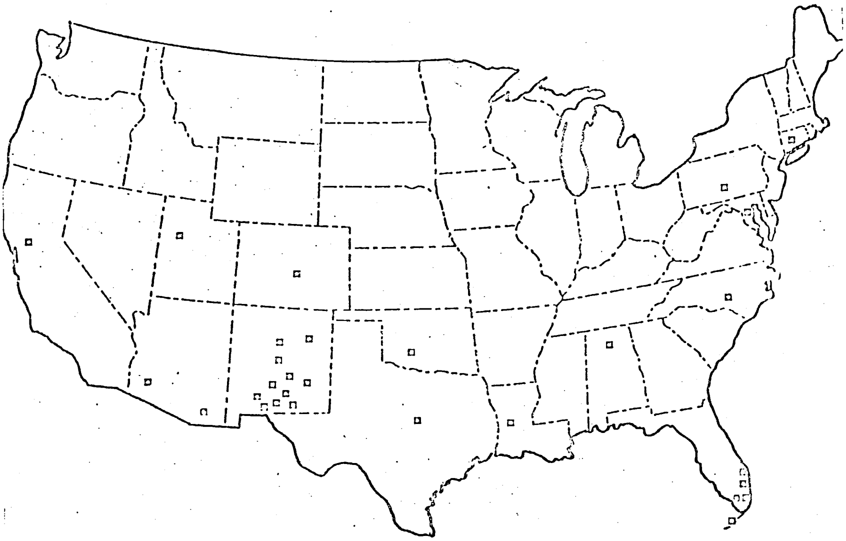

FIGURE 3.—High power Army emitters.

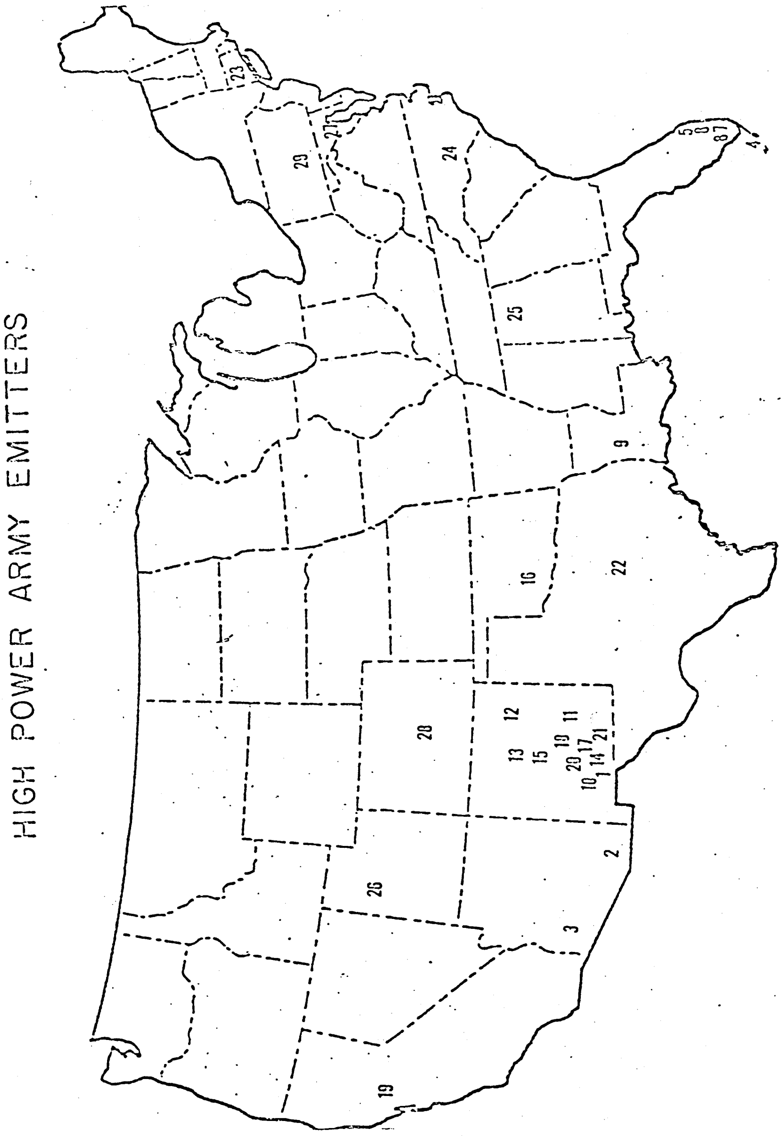
HIGH POWER ARMY EMITTERS

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FIGURE 4

FIGURE 5.—*Determinants of microwave bioeffects*

Power Duration Frequency Modulation Geometry	Characteristics of the radiation
Energy capture Induced microwave field Temperature Organ Tissue Cell Molecule	Characteristics of the biosystem

FIGURE 6.

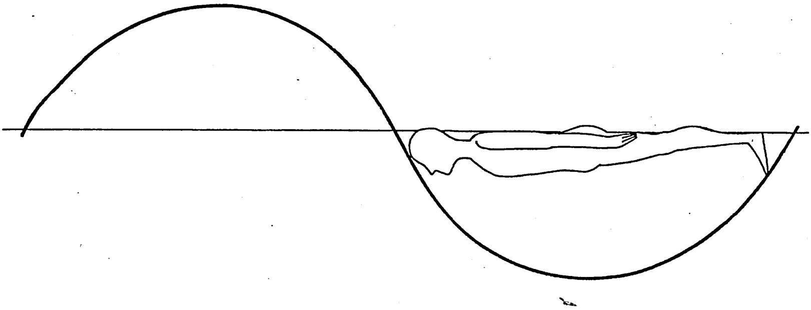
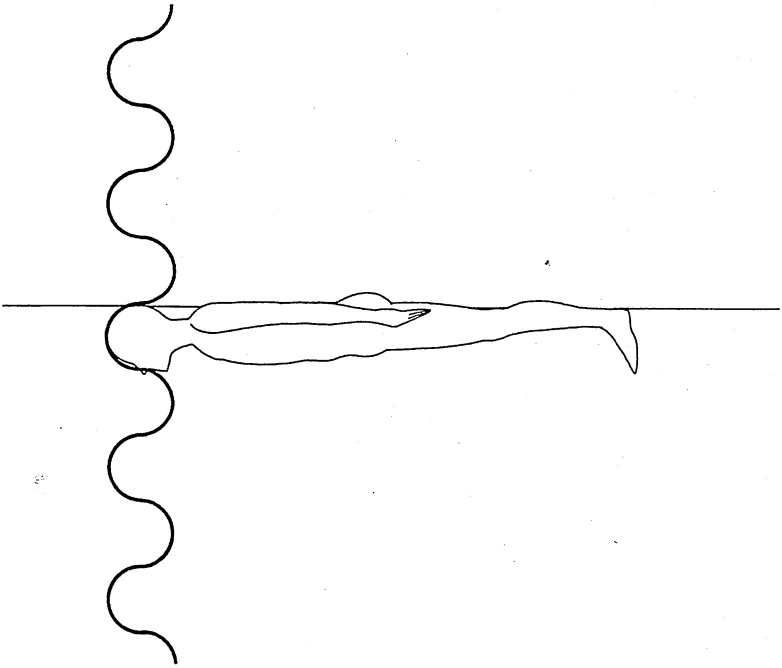


FIGURE 7



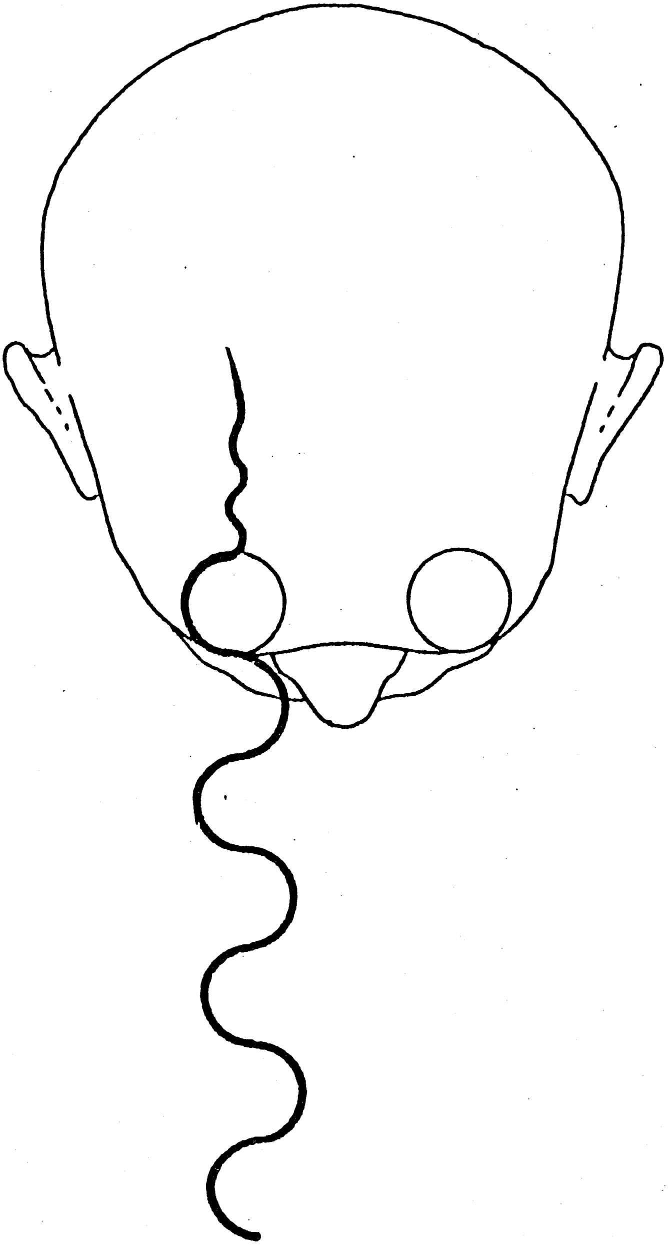


Figure 8

FIGURE 9

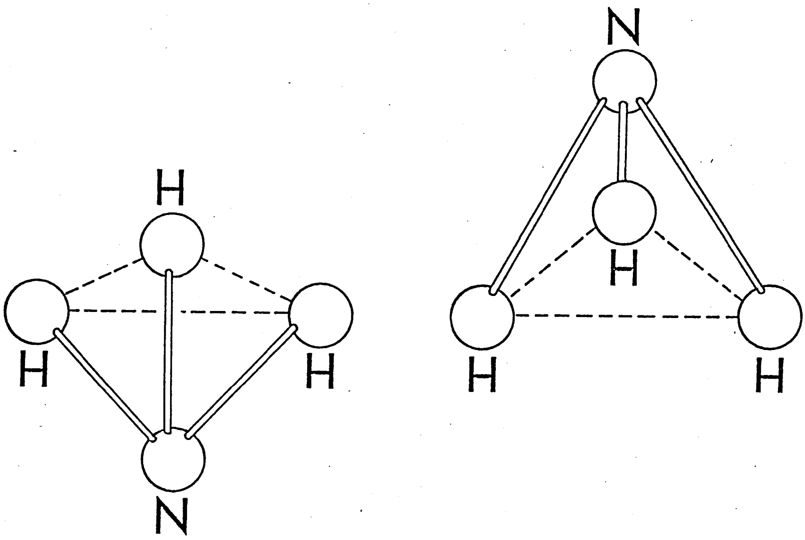


FIGURE 10. Management strategy

Identify effect:
    Continuous or pulse?
        Importance of frequency power, etc.
            Army spectral utilization
            Define limits of the effect
Examine biophysical mechanism:
    Enhance predictive value
        Prompt response to EW, ECM
            New Army systems
    Analysis of effect at all levels of biosystem organization
Determine medical hazard:
    Organ and tissue involved
    Functional implications

FIGURE 11. Major program blocks

1. Energy distribution and measurement
2. Biophysical actions of microwaves
3. Bioeffects of pulsed radiation
4. Behavior and other studies
5. Extramural programs

FIGURE 12. Program accomplishments with future research directions

1. A rational management strategy has been developed for intramural and extramural research to determine potential microwave hazards.

2. Methods for the measurement of tissue microwave properties have been established.

3. Methods have been developed for precise, continuous measurement of temperature changes in the organs of exposed subject animals.

4. The feasibility of nonsurgical methods for the measurement of microwave energy deposition by complex computer analysis has been established.

5. Microwave effects on basic biological processes in animals have been demonstrated.

FIGURE 13. Program accomplishments with future research directions

6. The unique hazards of exposure to pulsed microwave radiation, as compared to continuous microwave exposure of the same frequency and average power has been reported.

7. Behavioral effects of microwave exposure have been identified.
8. The importance of antennalike properties of animals and their organs has been demonstrated. This results in frequency specificity of microwave bioeffects.
9. No unique association was found between occupational microwave exposure and cataract formation.
10. New potentially beneficial diagnostic and scientific medical applications of microwaves have been identified.

[The following information was subsequently received for the record:]

Department of the Army,
Walter Reed Army Institute of Research,
Walter Reed Army Medical Center,
Washington, D.C., September 1 1977.

Hon. Warren G. Magnuson,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Mr. Chairman: In order to facilitate an orderly reply to the additional questions from the radiation oversight hearings, I will format this letter to include a direct quotation of the question prior to its response.

Question. In your testimony, you stated that current frequency dependent studies have expanded to "include the basic units of biology, cells and molecules." Does this mean that you are studying microwave effects on DNA and RNA? Please describe these studies in more detail.

Answer. The key words in this question are "microwave effects" on the respective nucleic acids DNA and RNA. This implies the use of microwave radiation to induce a change in the functional properties of the genetic material in cells and/or organisms. The Microwave Research Department has no elements of the intramural or extramural program which are directed to the objective of microwave induced alteration in the genetic material of cells or organisms.

This department has, however, made preliminary studies of bases, base pairs, nucleotides and various combinations or polymers of these compounds. The objective in these studies is to explore by electromagnetic means the physical-chemical properties of these molecules as examples of biopolymers where conformational states are well documented. In other words, the answer to your question is both yes and no: We are studying nucleic acids, but not from the aspect of microwave induced functional alternations.

Question. You mentioned experiments indicating aversive behavior by rats when irradiated in microwave fields. Have such effects ever been observed in humans. primates, or large mammals? Please provide citations to references where appropriate.

Answer. Microwave conditioned aversion has not, to my knowledge, ever been observed in species other than the laboratory rat. It may be worth emphasis to note that these aversion experiments are not to be construed as anything other than use of the laboratory rat as a biosensor for the presence of microwave energy. One way to test for the animal's ability to detect microwave energy is to test for motivational properties by aversion.

Question. You refer to techniques for non-invasive, three dimensional, mapping of microwave energy distribution in a living animal. How is this achieved? How accurate are these techniques? Can they be applied safely to the monitoring of human workers in an occupational setting? Have these techniques ever been used with humans?

Answer. The non-invasive mapping of microwave energy *in situ* is still in the phase of a feasibility study. The exact technology is still under development and revision, but in general the technique depends upon the fact that electromagnetic energy distribution in living organisms and tissues may be described by a set of microwave network parameters which define energy flow into the object under study in terms of reflection and transmission. In other words, if we know how much energy went toward the object from the transmitter and how much energy emerges from the object at the receiver, we can make statistical inferences about what happened within the object placed between the two antennas. As many observations of this sort are made by viewing the object from various directions, an increasingly complete description of the microwave patterns in the object is available.

The accuracy of the technique cannot be stated without many technical qualifications and additional data. However, in simple multilayered targets, the method can discriminate two 1.8 mm modeled blood vessels embedded in modeled fatty tissue with vessel separation in the order of 5–7 mm. In the case of a single target, we can discriminate the nature of the fluid inside of a large vessel (8 mm diameter) model in terms of whether it is filled with alcohol, water or salt solutions. In both cases, the targets were placed under water to simulate conditions in high loss tissue.

We have high expectations that spatial resolution and tissue typing accuracy will be improved with further research. However, at the moment we see no application for monitoring field levels inside of human workers in an occupational setting. The main limitation in this application is the need to maintain accurate antenna alignment relative to the object under study. This cannot be done with a moving target unless the antennas were attached to the person. The idea is interesting, but impractical. We see future applications moving to other areas such as the determination of organ specific field induction in radar operators under defined exposure conditions; and as a means to develop diagnostic information by electrographic microwave imagery in soft tissues where X-ray studies are not useful. The microwave levels such a procedure would employ are well below the safety standard.

These techniques have not been used with humans or any other living organism, so far only models of tissue. Furthermore, there are no present plans for human experimentation of any kind in this department.

Question. During the hearing you mentioned the unique hazards of exposure to pulsed microwave radiation as compared to continuous wave. What do you mean by unique hazards of pulsed microwave radiation? What reports were you referring to?

Answer. The questions of unique hazards due to pulsed radiation can be approached from at least two directions: One of these is the notion that there is a class of bioeffects due to pulsed radiation that are not associated with continuous fields. At the present time, the best example of this assertion is the phenomenon of thermoacoustic expansion. In other words, the rapid increase of induced fields from zero to a high value causes a pressure wave in the object which produces physical expansion and transmission of acoustic bulk and surface waves. The basic reference is a journal article by K. R. Foster and E. D. Finch in *Science*, Vol. 185, pp. 256–258, 1974.

Another way the question may be approached is from the point of view of the safety standard. No present U.S. safety standard describes fields in terms other than average power. This description is wholly inadequate for pulsed fields since the peak power and rise time are hopelessly confounded with duty cycle and time averaged wave forms.

Question. What behavioral effects of microwave exposure have been identified? Please provide citations to references where appropriate.

Answer. The behavioral effects of microwave radiation have been the subject of many research studies over the past 3 decades.

One place to begin a review of Western findings is the proceedings of the USNC/URSI 1975 annual meeting. There are two volumes on microwave bioeffects in which several papers and their references are available. This source is "Biological Effects of Electromagnetic Waves," Editors, C. C. Johnson and M. L. Shore, published by the Bureau of Radiological Health, HEW Publication (FDA) 778010. A convenient source for Eastern Block findings is a book by A. S. Pressman entitled "Electromagnetic Waves and Life" published by Plenum Press, New York, 1974.

I must emphasize that neither of these sources should be regarded as gospel. Microwave research is a technically demanding subject which is fraught with irreproducibility, poor dosimetry, artifactual results and frequent lack of adequate scientific standards even in long established journals. In other words, the interpretation of published literature in this subject requires expert consultants.

Question. During your testimony you stated that the antenna-like properties of animals and their organs have been demonstrated. Please specify the studies in which these properties have been demonstrated.

Answer. The antenna-like properties of animals has been largely the work of O. P. Gandhi. Much of his research was performed at Walter Reed Army Institute of Research under Army contract. The basic publication may be found in the *Annuals of the New York Academy of Science*, Vol. 247, pp. 532–538, 1975.

Question. You mentioned emerging technologies involving potentially beneficial diagnostic and scientific medical applications of microwaves. Please describe in more detail.

Answer. The subject of emerging technology for diagnostic and scientific medical applications of microwave and RF radiation is an item of great importance in current research. The applications I could cite run the gamut from promising basic research to rather speculative therapeutic applications. Research in the former category includes the use of microwave and RF energy to measure the functional status of cells and organs. This type of application makes use of the fact that non-invasive electromagnetic measurement of the frequency dependent properties of cells appears to directly interrogate physiological properties of the cell membrane. There is the distinct possibility that this type of information may be implemented in a system with imaging capabilities. If this should become a reality, then non-invasive analysis of cellular functional status in deep organs such as heart, liver and kidney may be presented as images. The potential diagnostic value is great in that this type of information is not available with present medical imagery methods such as x-ray and ultrasound.

An example of speculative therapeutic applications is a French report that a certain parasitic infestation (trypanosomyasis) may be treated with microwave exposure such that survival rates in laboratory animals is improved. There are also reports of successful cancer treatment with local temperature elevation (hyperthermia) produced by microwave exposure. Once again, I must caution the Committee that these therapeutic applications are based on isolated reports without detailed biophysical or clinical control. As a result, I suggest that these findings be viewed with a healthy incredulity. However, I am not suggesting that the possibility of therapeutic applications should be ignored. Indeed, our basic research efforts may produce the data base necessary to properly explore such applications in future years.

A possibly less speculative therapeutic application with special military relevance is the use of microwave and RF exposure to accelerate wound healing and reduce inflammation. If these applications are well founded, then use in burn treatment would be especially attractive.

In conclusion, I would like to thank the Committee for this opportunity to elaborate on my testimony. Indeed, I welcome the opportunity to balance the issue of hazards and public safety with the prospect for potentially beneficial applications for this form of electromagnetic energy with its unique relevance to biological systems.

Sincerely yours,

LAWRENCE E. LARSEN, M.D., (Maj. M.C.),
Chief, Department of Microwave Research.

Senator FORD. We will move on to the next witness.

I will then have general and specific questions.

Captain Tyler?

Captain TYLER. Mr. Chairman, it is a pleasure to appear here today and have the opportunity to provide you with an overview of the Navy's research program in nonionizing electromagnetic radiation.

In 1970, the Bureau of Medicine and Surgery determined that the need for medical/biological information concerning the effects of nonionizing radiation was of sufficient urgency and importance to warrant extraordinary attention and emphasis.

To meet this need, the Surgeon General issued an instruction establishing the Electromagnetic Radiation (EMR) Project Office.

The Navy medical research program is closely coordinated with the Army and Air Force through the Tri-Service EMR Panel and with other Federal agencies through the "Interagency side effects working group" of the Office of Telecommunications Policy.

I would like to point out, in my personal opinion, this program is probably by far the best coordinated research program within the Federal Government at the present time.

The tri-service program is responsive to the Electromagnetic Radiation Management Advisory Council's recommendations of 1971. In turn, the specific Navy program is based upon the tri-service program with emphasis on the areas that are considered important to the Navy such as "Project Seafarer," and also where we have specific in-house capabilities.

The Navy's major efforts are in two areas: The microwave area and the extremely low-frequency area.

First, I would like to briefly cover our program in ELF. Since 1968, the Navy has conducted over 45 separate biological/ecological research projects at a cost of about $4 million. Prior to commencing biological research, the Navy conducted several literature surveys of research on the biological effects of low frequency electromagnetic radiation.

At that time, very little research was identified that was directly relevant to the proposed Navy extremely low-frequency communication system, as most of the research conducted was concerned with high voltage systems such as power generating plants and high voltage transmission lines.

The research has explored the following areas: Physiology, biochemistry, behavior, growth and development, biological rhythms, human performance, genetics, and ecology.

In May 1975, the Assistant Secretary of the Navy (Research and Development) requested the National Academy of Sciences to review the entire ELF biological/ecological research program.

In December 1976, the National Academy of Sciences issued a 4-page interim report which stated that there did not appear to be any cause for concern that this ELF system would adversely affect humans or the environment. The final report is expected sometime this summer.

In the meantime, the Navy has also reviewed available data and has prepared a draft environmental impact statement which was released in February of this year. Presently, we are continuing research in this area. Additionally, the Navy plans to respond to the National Academy of Sciences recommendations as may be appropriate.

In the area of microwaves, the goal of the Navy's program is the development of criteria for use in the establishment of standards, limitations, and design guidelines intended to protect personnel in the naval environment and the coexisting general public.

The formulation of any standard requires that thresholds for biological effects be determined for the appropriate frequency ranges and modulation characteristics. To adequately determine the biological effects, parameters noted by Dr. Larsen in his testimony must be closely controlled and evaluated.

Since each factor can have many values, the potential combinations and permutations are, for practical purposes, infinite. It is easy to see why nonionizing electromagnetic radiation is far more complex than ionizing radiation. To complicate matters even further, the various portions of the spectrum require different radiating and exposure facilities. Thus, what is needed for a microwave biological experiment is entirely different than that required for an ELF experiment.

Since the basic mechanisms of interaction other than thermal are unknown, the problem can be approached in two ways: (1) basic research to determine the fundamental mechanisms of interaction between EMR and biological systems: and, (2) a pragmatic, systematic approach.

The Navy is supporting a small program of fundamental research to elucidate if other than thermal mechanisms can account for observed effects. Research studying fundamental mechanisms, depends a great deal on the insight, ideas, and competence of the individual investigator conducting the research.

Present evidence indicates that major biological mechanisms of EMR may be the results of interaction with membranes and its associated structures. Therefore, our efforts are directed toward the elucidation of effects on cellular membranes, subcellular particles, and complex macromolecules.

Since there is no way to predict when a major breakthrough will be made in determining the basic mechanisms, the major emphasis of our program is on the pragmatic, systematic approach.

We have limited our pragmatic approach to five separate areas of concern: The central nervous system; behavior; immunology/hematology; occular; and dosimetry and energy distribution.

Again, there are more possibilities for research than available resources can support. Thus, a few effects have been selected for systematic study.

In the area of the central nervous system, we selected such effects as the histological changes in the CNS, alternations in the blood brain barrier, changes in the ion concentration and binding parameters, and observed alternations in neurohormones and neuroenzymes.

In the area of behavior, we are studying three broad areas: Cognitive, perceptual motor, and vigilance performance.

Research in dosimetry is concerned with determining the distribution of energy as a function of animal size and frequency of radiation, the influence of peak powers and pulse shapes, and the influence of electric versus magnetic fields in contributing to these effects.

Finally, the question of cataractogenic effects of nonionizing electromagnetic radiation must be resolved.

All of the present laboratory evidence indicates that thermal doses which raise the internal eye temperature to approximately 45° Celsius must be employed before a cataract is produced.

Still the question remains concerning chronic long-term exposure. Because of the time and cost involved in such a long-term study, the parameters that constitute the "worst case" must be used. The present Navy program is designed to elucidate some of these important factors by identifying the frequency and modulation dependence, the cataractogenic threshold for short-term exposure of various frequencies, and the identification of histological and ultrastructural changes in the lens.

The Navy research program is conducted at both in-house laboratories on contract at civilian institutions.

In addition to discussing the present research program, we have been asked to comment on the present state of knowledge and potential deleterious effects on nonionizing electromagnetic radiation. In simple terms, it is very confusing, although I must say that our knowledge is far greater today than it was 5 years ago.

Investigators have a greater awareness of the complexities of dosimetry and exposure requirements. We now know that for best results we should only use one animal per exposure chamber per experiment. Unfortunately, this method is impractical, very expensive, and impossible if you want long-term exposures of a large number of animals to provide statistical validity. Thus, we have had to compromise by using multiple animal exposures.

Excellent progress has been made to minimize field distortions under these conditions and to provide the investigators with a more accurate estimate of animal exposure.

There is some evidence that not only are there frequency dependency or "windows," where effects appear at some frequencies and not at others; but also there may be amplitude windows, where an effect is not present at low power levels. As the power increases, the effect appears, and then disappears again at higher power levels. What this means to man is unclear.

There are also suggestions that the height, rate of onset, and length of pulses may play a part in determining biological effects, but because of lack of sophisticated equipment, these parameters have not been adequately investigated.

Alterations in the permeability of the blood brain barrier has been noted using three different techniques in small animals. Again, thresholds for this effect have not been established, but current research is directed toward this goal.

There have also been several reports linking microwaves with several disease processes, particularly cataracts and heart disease. I would like to point out that these reports are case reports and in no way provide any scientific evidence as to a cause and effect relationship.

To really answer this question, two approaches can be used: laboratory research and epidemiology studies. As noted previously, laboratory studies to date have indicated that thermal levels must be reached before cataracts can be produced. Even in animals such as the rabbit, this requires an excess of 100 milliwatts per centimeter squared—an exposure so high, that unless the rest of the animal's body is shielded, he succumbs to the high thermal stress from the whole body exposure.

The second approach is an epidemiology study of exposed personnel. To place these epidemiological studies in a proper perspective, I have in my formal testimony quoted a few paragraphs from the classic textbook on preventive medicine, which notes there are two fundamentally different approaches.

One is a prospective study, look forward, by taking a group of people today and look forward in time.

The other is a retrospective study, where you take a group of people today with a disease and go back into their history and look for correlations.

Presently, there is little evidence there is a specific "microwave disease," or that if there is one, it certainly has a low incidence, and there is no evidence of having a short time interval between exposure and the onset of the disease.

Unlike the ionizing field where individual exposure data is mandatory and religiously maintained, there are none for personnel exposed to nonionizing electromagnetic radiation.

With the present lack of identifiable disease states which result from low-level exposure in a relatively short period of time, it is considered to be more cost effective to utilize available funds for laboratory research to adequately determine and characterize biological effects prior to attempting epidemiological studies.

As to the needs for the entire nonionizing electromagnetic radiation area, the original research recommendations made by ERMAC in 1971 are as relevant today as they were then.

Recently, ERMAC has again completed another series of extensive reviews of all the Federal agencies' programs in this area, and is preparing to update the research guidelines in light of current knowledge and the present agencies' programs.

In conclusion, Mr. Chairman, the Navy feels it has a responsive program directed toward the solution of the Navy problems. This program is also well coordinated with the other Federal agencies through OTP. There still is a need for additional funding to acquire the knowledge within a reasonable period of time.

I will be happy to try to answer any questions you or the committee may wish to ask. Thank you.

[The statement follows:]

STATEMENT OF CAPTAIN PAUL E. TYLER, MEDICAL CORPS, U.S. NAVY; DIRECTOR ELECTROMAGNETIC RADIATION PROJECT OFFICE, NAVAL RESEARCH AND DEVELOPMENT COMMAND

Mr. Chairman, it is a pleasure to appear here today and have the opportunity to provide you with an overview of the Navy's research program in nonionizing electromagnetic radiation. The Surgeon General, in response to your letter of May 20, has also provided written information on the Navy's medical efforts in this area.

In 1970, the Bureau of Medicine and Surgery determined that the need for medical/biological information concerning the effects of nonionizing electromagnetic radiation was of sufficient urgency and importance to warrant extraordinary attention and emphasis. To meet this need, the Surgeon General issued an instruction establishing the Electromagnetic Radiation (EMR) Project Office. The Director of the EMR Project Office provides a centralized point of contact within the Navy for coordination and integration of the Navy's medical research program in all areas of radiation, with particular emphasis on nonionizing electromagnetic radiation. He also functions as the primary point of contact for liaison outside the Navy.

The use of the Project Office as a management technique in areas of high interest is common in the systems commands for major hardware development. But, the EMR Project Office was the first, and to date the only, project office within the Bureau of Medicine and Surgery. This is an indication of the vital interest the Navy has in this area.

The entire Navy medical research program is closely coordinated with the Army and Air Force through the Tri-Service EMR Panel and with other federal agencies through the "Interagency Side Effects Working Group" of the Office of Telecommunications Policy (OTP). It should be noted that through OTP, this program is by far the best coordinated biomedical research program within the federal government. Most Departments and Agencies have developed points of contact for this program and there is a constant and active interchange between the various agencies. The Tri-Service program is responsive to the Electromagnetic Radiation Management Advisory Council (ERMAC) recommendations. In turn, the specific Navy program is based on the Tri-Service program with emphasis on areas that are considered important to Navy systems; e.g., Project Seafarer, and where we have specific in-house capabilities.

The two major research efforts of the Navy medical program have been in areas of microwaves and extremely low frenquency (ELF). The ELF program has been in direct support of the Navy's Project Seafarer Communications System. Resumes of our medical research projects have been provided this Committee as an enclosure to the Surgeon General's letter of 6 June 1977.

Presently, the total Navy funding level is approximately 3.4 million dollars, with 1.5 million sponsored by the Navy Electronic Systems Command for biological and ecological studies in support of Project Seafarer. The remaining 1.9 million are funds provided by the Naval Medical Research and Development Command and the Office of Naval Research for microwave research.

I would first like to cover the Navy's program in ELF.

Since 1968 the Navy has conducted over 45 separate biological/ecological research projects at a cost of about 4 million dollars. Prior to commencing biological research, the Navy conducted several literature surveys of research on the biological effects of low frequency electromagnetic radiation. At that time very little research was identified that was directly relevant to the proposed Navy extremely low frequency (ELF) communication system, as most of the research conducted was concerned with high voltage systems such as power generating plants and high voltage transmission lines.

Research sponsored by the Navy in support of its ELF communications system has been conducted within Department of Defense laboratories and civilian institutions—primarily within the academic community. The research has explored the following major areas: physiology, biochemistry, behavior, growth and development, biological rhythms, human performance, genetics, and ecology.

In February 1975 the EMR Project Office published a two-volume compendium of all the available research reports. The compendium was published to facilitate easy access to all pertinent ELF biological/ecological research conducted by the Navy. In January 1977 a third volume was published containing all of the research reports that had been completed or published since the first two volumes were issued.

In May 1975 the Assistant Secretary of the Navy (Research and Development) requested the National Academy of Sciences to review the entire ELF biological/ecological research program. The Academy agreed to accept the following tasks: assess the adequacy of existing knowledge and data as a basis for determining biological/ecological effects of ELF radiation; identify any critical or potentially critical areas where data is inadequate for purposes of determining biological/ecological effects; recommend research projects best designed to acquire the needed data; and, identify those biological/ecological effects, if any, which may be of major concern.

In December 1976 the Academy issued a four-page interim report which stated that there did not appear to be any cause for concern that this ELF system would adversely affect humans or the environment. The final report is expected sometime this summer.

In the meantime, the Navy has also reviewed available data and has prepared a draft Environmental Impact Statement which was released in February of this year. Presently we are continuing research in this area. Additionally, the Navy plans to respond to the National Academy of Sciences recommendations as may be appropriate.

In summary, the effects of the interaction of electromagnetic fields of all types with living organisms are of general scientific interest and importance. Scientific investigations have not yet provided a generally acceptable theory of prediction of biological effects. Extremely low frequency electromagnetic fields exist in nature, and artificial fields are in common worldwide use.

Although research to date does indicate the existence of some rather diverse and subtle effects associated with particular types of ELF exposure, no adverse biological effect has been substantiated or is considered probable from SEAFARER system operation.

The present funding level for biological/ecological studies is 1.019 million dollars. While 490 thousand dollars is being spent on environmental surveys and the writing of the Environmental Impact Statement.

In the area of microwaves, the goal of the Navy's program is the development of criteria for use in the establishment of standards, limitations, and design guidelines intended to protect personnel in the naval environment and the coexisting general public. In reaching this goal, the following objectives have been established: develop a coordinated, interdisciplinary, scientifically sound program of research and development designed to determine the biological effects of non-ionizing electromagnetic radiation; determine the thresholds of these effects in terms of electromagnetic field parameters relevant to Navy transmitting systems; development of procedures and techniques for the extrapolation of experimental results to man; and, determination of the mechanism(s) of interaction of non-ionizing electromagnetic radiation with biological systems.

The formulation of any standard requires that thresholds for biological effects be determined for the appropriate frequency ranges and modulation characteristics. To adequately determine the biological effects the following parameters must be closely controlled and evaluated:

(*a*) Frequency: Single—Multiple.

(*b*) Wave form: Continuous wave (CW) (unmodulated/modulated); pulse (repetition rate, pulse width, peak power, modulation).

(*c*) Exposure time: Daily—Duration of experiments.

(*d*) Energy density level: External (incidence level); internal (specific absorption rate).

(*e*) Exposure geometry.

(*f*) Animal size (species).

Since each factor can have many values, the potential combinations and permutations are, for practical purposes, infinite. It is easy to see why non-ionizing electromagnetic radiation is far more complex than ionizing radiation. To complicate matters even further, the various portions of the spectrum require different radiating and exposure facilities; thus what is needed for a microwave biological experiment is entirely different than that required for an ELF experiment.

To date many potentially significant biological effects have been reported in the literature or at scientific meetings. None of these findings have been adequately evaluated. Before this can be done, the following questions must be answered: What is the threshold for the effect? Is there a frequency dependence? If so, what is it? Is there a time dependence? Are there other parameters that effect the biological response? What are they? What parameters must be used to extrapolate animal data to man?

The majority of these questions would be relatively easy to answer if we knew the mechanisms of interaction between electromagnetic radiation and biological systems. It is my opinion that some of the recently reported findings cannot be fully explained by the classical theory of thermal interactions. While many of the reported effects remain unverified, some have been verified by more than one investigator in different laboratories. Since the basic mechanisms of interaction other than thermal are unknown, the problem can be approached in two ways: (1) basic research to determine the fundamental mechanisms of interaction between EMR and biological systems; and (2) a pragmatic, systematic approach to answering the previous questions.

The Navy is supporting a small program of fundamental research to elucidate if other than thermal mechanisms can account for observed effects. Research studying fundamental mechanisms, depends a great deal on the insight, ideas, and competence of the individual investigator conducting the research. Some research in this area is theoretical and some are laboratory efforts. Present evidence indicates that major biological mechanisms of EMR may be the results of interaction with membranes and its associated structures. Therefore, our efforts are directed toward the elucidation of effects on cellular membranes, sub-cellular particles, and complex macromolecules.

Present research includes the evaluation of effects upon cellular components of muscle cells, differing effects between electric and magnetic fields and effects upon synthetic and biological membranes and macromolecules. Since there is no way to predict when a major breakthrough will be made in determining the basic mechanisms, the major emphasis of our program is on the pragmatic, systematic approach.

While both the ERMAC recommendations and the Tri-Service program list many areas where research is needed, the vast array of possible research in these areas is far greater than the current Navy budget and other resources can cover. This, plus the fact that other agencies are also conducting extensive research in EMR makes it mandatory that a strict selection be made of what research to support.

The EMR Project Office has limited its pragmatic program to five areas: central nervous system (CNS); behavior; immunology/hematology; ocular; and, dosimetry and energy distribution.

The following scheme is being used to characterize the biological effects. The first step is to establish the dose threshold for the onset and/or appearance of the effect for a given set of exposure parameters. The third step is to investigate the frequency dependence of the threshold. Finally, a three-dimensional plot will be developed to describe the relationship between dose, time and frequency. If other factors are determined to be of critical importance they will be investigated in a similar manner to identify the dose threshold.

In this pragmatic approach, again there are more possibilities for research than available resources can support. Thus, a few reported effects in each of the five areas have been selected for systematic study. For the central nervous system the following effects have been selected for continued research: histological changes in the CNS; alterations in the electroencephalograph and sleep-patterns; alteration in the blood brain barrier; changes in ion concentration and binding parameters; and, alterations in neurohormones and neuroenzymes.

We are presently investigating three general areas of behavior: cognitive, perceptual motor, and vigilance performance.

This past year we instituted and are still developing a major effort in the immunological area. Research emphasis is being placed in the evaluation of: cellular transformations; effects upon cellular morphology; alterations in complement receptors; changes in the metabolic activity of white blood cells; alterations in serum proteins; and, changes in "B" and "T" cell populations of lymphocytes.

Research in dosimetry and energy distribution is concerned with determining the distribution of energy as a function of animal size and frequency of radiation, the differences in distribution of energy within an animal as a function of different modulation; the influence of peak powers and pulse shapes, and the influence of electric versus magnetic fields in contributing to biological effects.

Finally, the questions of cataractogenic effects of non-ionizing electromagnetic radiation must be resolved. All of the present laboratory evidence indicates that thermal doses which raise the internal eye temperature to approximately 45° Celsius must be employed before a cataract is produced: Still the question remains concerning chronic long-term exposure. Because of the time and cost involved in such a long-term study, the parameters that constitute the "worst case" must be used. The present Navy program is designed to elucidate some of these important factors by identifying the frequency and modulation dependence, the cataractogenic threshold for short-term exposure of various frequencies, and the identification of histological and ultrastructural changes in the lens.

The Navy research program is conducted at both in-house laboratories and on contract at civilian institutions. Our major facility is at the Naval Aerospace Medical Research Laboratory (NAMRL) in Pensacola, Florida. Presently, we are in the process of increasing our capability at the Naval Medical Research Institute (NMRI) in Bethesda, Maryland. There is a critical need to increase the exposure facilities at NMRI. In Fiscal Year 1978 an additional 1.5 million dollars is required to provide for exposure chambers and radiating equipment. This is a one-time requirement. In addition, there is a continuing requirement to increase the EMR Project Office program by a minimum of 600 thousand dollars per year to be able to adequately research the identified areas of Navy interest.

It is important to keep in mind the difference between the various parts of the electromagnetic spectrum. The two major classes, ionizing and non-ionizing, are as different as night and day. We know that ionizing radiation can cause severe biological damage and we have accepted theories as to the mechanisms of damage. Ionizing radiation has been extensively investigated, especially over the past 30 years. There has been tremendous financial investments with large laboratories devoted to its study, such as Brookhaven, Lawrence Radiation Laboratories, Oak Ridge, etc. Despite this tremendous investment of resources there are still many unanswered questions concerning ionizing radiation and its effect upon biological systems. It is estimated that in Fiscal Year 1977 alone an excess of 100 million dollars is being spent continuing to investigate ionizing radiation.

On the other hand, non-ionizing electromagnetic radiation research is a mere infant in comparison. First and foremost we have no accepted theories as to damage production by any mechanism other than thermal. Many scientists have been reluctant to enter this particular field of research because of the prevailing feeling that all effects were thermal in nature and at the lower frequencies there was little or no interaction with the body, so why bother to look at an area so uninteresting. Thus, where you count the investigators in ionizing radiation by the hundreds and thousands, the scientists involved with non-ionizing electromagnetic radiation can be counted by the tens.

Fortunately, non-ionizing electromagnetic radiation research is beginning to mature. More people are interested, better facilities have been and are being developed, and the quality and quantity of research has vastly improved over the past five years. Presently, the problem is far more complex than that of ionizing radiation, as there are no accepted theories of interaction other than thermal. Yet, there are several experiments whose results cannot be explained by thermal means. I think it is these experiments that is stimulating the interest of new and capable researchers to enter this field.

The answer will not be here tomorrow or next year; in fact, it may be many years. Look at the ionizing field—it is going strong after 30 years. How long it takes will depend upon the commitment of resources and some luck, for who knows that tomorrow a brilliant breakthrough will not take place and advance our knowledge many years. Since one should not plan on these quirks of brilliance, we must plan to substantially increase our efforts in this area if we expect to realize achievable goals in the near future.

This is not to say that the resources should match, or even come close to, those of ionizing radiation. While the area of non-ionizing has more unanswered questions than ionizing, it is not as severe a problem, and it does not involve the dangers that are inherent with ionizing radiation.

If each Department or Agency's budget for this area were tripled starting in Fiscal Year 1978, there would be significant contributions within the next five years. There may even be enough data by then to develop rational exposure standards, at least, for the microwave portion of the spectrum.

Mr. Chairman, in addition to discussing the present research program, we have been asked to comment on the present state of knowledge and potential deleterious effects of non-ionizing electromagnetic radiation. In simple terms, it is very confusing. Although I must say that our knowledge is far greater today than it was five years ago. Investigators have a greater awareness of the complexities of dosimetry and exposure reqnirements. We now know that for best results we should only use one animal per exposure chamber per experiment. Unfortunately this method is impractical, very expensive, and impossible if you want long-term exposures of a large number of animals to provide statistical validity. Thus, we have had to compromise by using multiple animal exposures. Excellent progress has been made to minimize field distortions under these conditions and to provide the investigations with a more accurate estimate of animal exposure.

We are now beginning to develop methods for determining the radiation absorption and distribution at the tissue and organ level rather than just the incident exposure levels. The major problem in this area is the inability to extrapolate animal findings to man. The available technology is very simplistic and does not address many of the factors required for extrapolation. We do know that there is a frequency dependence, but the exact relationship is unknown. We know that observed effects differ when the irradiation is continuous wave or pulsed and there are some indications that modulated signals have different effects than unmodulated signals.

There is some evidence that not only are there frequency windows—where effects appear at some frequencies and not at others; but also there may be amplitude windows—where an effect is not present at low power levels, as the power increases the effect appears, and then disappears again at higher power levels. What this means to man is unclear. There are also suspicions that the height, rate of onset, and length of pulses may play a part in determining biological effects; but, because of lack of sophisticated equipment, these parameters have not been adequately investigated.

Obervations in some studies have shown the delayed onset of an effect following irradiation. For example, it has been noted that some immunological changes in white blood cells are not apparent until some five days following irradiation. While the dose levels to date have been such that they may produce a thermal burden on the animal, we do not know the threshold nor can we explain the five-day delay. If it was a direct thermal effect, one would expect to see immediate changes and not a delay of five days.

Alternations in the permeability of the blood brain barrier has been noted using three different techniques in small animals. Again, thresholds for this effect have not been established. Whether it happens in larger animals and how to relate it to man is totally unkown.

In addition to these blood brain barrier changes, brain structural changes have also been observed in small animals subjected to irradiation incidence levels in the 10 to 20 milliwatt range. Studies currently underway indicate that these levels may be thermal doses to the animal and producing specific "hot spots" in the brain. But, again, the threshold for these structural changes has yet to be determined, as does the effect for long-term exposure.

Many investigators have reported various behavioral changes using a wide variety of exposure parameters and conditions. Here again threshold levels for the onset of the change are almost non-existent, and because of the dissimilarity of the many experiments, the correlation between one experiment and another is very difficult. What does this mean in terms of man? No one can really say today.

There have been several reports both in the lay press and medical journals linking microwaves with several disease processes, particularly cataracts and heart disease. I would like to point out that these reports are case reports and in no way provide any scientific evidence as to a cause and effect relationship. For example a few cases of cataracts in persons owning microwave ovens have been reported, but there are thousands of people with microwave ovens without cataracts; likewise, there are many people with cataracts who have never been exposed to microwaves.

To really answer this question, two approaches can be used. Laboratory research and epidemiology studies. As noted previously, laboratory studies to date have indicated that thermal levels must be reached in the eye before cataracts are produced. Even in animals such as the rabbit, this requires an excess of 100 milliwatts per centimeter squared—an exposure so high, that unless the rest of the animal's body is shielded, he succumbs to the high thermal stress from the whole body exposure.

There is a need for chronic long-term exposures in the laboratory to finally answer this question. This will require a large number of animals for both experimental and control groups. Additionally, one should utilize the most critical parameters as noted before. Until now facilities have not been available which could adequately irradiate many animals at once. Presently one long-term study is underway at the University of Washington, but I am not sure that all of the critical parameters are currently being investigated.

The second approach is an epidemiology study of exposed personnel. To place epidemiologic studies in a proper perspective, I would like to quote a few paragraphs from a classic textbook on preventive medicine (Maxcy & Rosenau's "Preventive Medicine and Public Health," Appleton-Crofts, New York, 1973):

"Two fundamentally different approaches can be taken in formal epidemiologic studies. One, commonly known as the prospective or cohort approach, seeks to test the association of an attribute with a disease by identifying those members of a population now free from the disease, according to whether they possess the attribute, and following them over a period of time so as to detect the cases as they arise and to generate comparative incidence rates among those having the attribute and those who do not have it. The second approach, widely known as the retrospective study but more appropriately termed the case-control or case-history study, begins by identifying a series of cases of the disease under investigation and a control group of persons free from the disease; it then proceeds to a comparison of the frequency with which each group manifests the attributes of interest, which may be contemporary or historical.

"Perhaps the most widely known illustration of these two contrasting approaches is the issue of smoking and lung cancer. Ideally this issue would be resolved by a human experiment, which should leave no uncertainty. Such an experiment, however, would be both unethical and impracticable. The first studies, stimulated by the apparent increase of the disease, were of the case-control variety in which lung cancer patients and hospitalized controls were queried as to their smoking histories. Many such studies were done, and all demonstrated an association of smoking and cancer. They were succeeded by several prospective studies, in which smoking histories were taken on large numbers of healthy men who were then observed over a period of years. The prospective studies fully supported the case-control studies.

"Observational studies can often establish determinants of disease beyond a reasonable doubt, but never beyond all doubt. The logical possibility remains that the association seen is an indirect one—in the case of smoking and cancer, for instance, that there is some as yet unidentified factor associated both with the disease and with smoking which is the real cause of the apparent linkage. Replication of the findings in various ways by various different investigators has eliminated the possibility that the findings are spurious in the sense of being due to poor methods. Search for some hidden carcinogenic factor among smokers has as yet failed to reveal any, although psychological differences are evident. Support for the smoking hypothesis has come from the examination of qualitative and quantitative relationships. Pipe and cigar smokers, who generally do not inhale, also do not share the hazard; the risk increases with the number of cigarettes smoked; and ex-smokers experience rates that are intermediate between those of current smokers and nonsmokers. To these methods of validation of a hypothesis—replication of findings, search for hidden covariables, and quantitation of relationships—should be added, when possible, laboratory evidence bearing on the hypothesis. Lastly, the biologic reasonablenes of the hypothesis should be considered. This must be done with caution, for rejecting a finding because it seems implausible on the basis of present knowledge can be a deterrent to the acquisition of new knowledge.

"The choice between the two methods—the prospective and case-control methods—depends on the disease, its frequency, the nature of the attributes concerning which formation is sought, and the time intervals involved. For diseases of high incidence the prospective method is usually best. The selected population can be classified as to the attributes of interest without fear of bias. The necessary period of observation to onset of the illness may be short enough to minimize problems related to follow-up, such as loss to observation and changes in classification. An important advantage is that one may look for any disease or condition that may be associated with the factor; for instance, in a prospective smoking study the association of smoking with lung cancer, myocardial infarction, and chronic bronchitis could be detected, whereas in a case-control study there would need to be a hypothesis linking smoking with a specific disaese before a study could be recognized.

"The main and often decisive advantage of case-control studies is logistic. Rare conditions which can be presumed to raise long after the case began to operate are virtually impossible to investigate prospectively because of the enormous commitment of funds and manpower required, the difficulty of sustaining interest, and the problem of dropouts. Furthermore, answers to these problems cannot await such prolonged study. As an illustration, the latent period of solid tumors is thought to be generally 10 years or more; to identify a twofold increase in risk for a form of cancer having a low incidence would require observation for many-thousand person-years.

"In studying problems of human disease, Densen pointed out in previous editions of this book that the first step is formulation of the problem in such terms as will permit progress toward an answer. In fact, this is the most important step, for it serves to determine the study design and to guide the investigator the rest of the way. Before one can attack the hazards of ionizing radiation it is not sufficient to say 'ionizing radiation is detrimental to health and our aim must be to eliminate it.' We do not know if it is harmful at all levels, and we could not eliminate the so-called background radiation in any case. Existing information would permit us to say that radiation produces lethal acute effects, burns and local tissue damage, genetic damage, leukemia and other malignant disease, and probably a general life-shortening effect. Thus the statement that radiation is harmful is not particularly helpful. The kind of harm and, if possible, the amount of harm that results from a given amount of radiation of a particular kind must be specified."

While it is incidental that the authors selected ionizing radiation for their example, it is just as applicable to non-ionizing electromagnetic radiation. We must define the kind of harm and the level of exposure that results in the specific harm.

In the past there has been some criticism, particularly of the military, for failure to do what seemed obvious—looking at people. But, as can be seen from the excerpts noted above, several basic criteria must be met in order to have a scientifically valid study. Presently, there is little evidence that a "microwave disease" exists; or, if there is one, it has a high incidence and a short time interval between exposure and onset of the disease. Unlike the ionizing field, where individual exposure data is mandatory and religiously maintained, there are none for personnel exposed to non-ionizing electromagnetic radiation. In attempting to conduct retrospective studies, medical records are generally inadequate to be able to detect small differences. Even death certificates have been recognized as a source of significant errors if not backed by an autopsy.

Additionally, when one does not really know what you are looking for, and therefore looks for everything—the so-called "shotgun" approach—there is a far greater chance of having false-positive findings which then require additional time and money to prove that they were not valid observations.

A classical example of this was the apparent finding that there was a higher incidence of fathers of children with Downe's Syndrome (Mongolism) who were microwave workers. The study was designed to evaluate the incidence of maternal prenatal exposure to ionizing radiation. When the incidental finding concerning the fathers was noted, a new study was designed to specifically evaluate the occupations of fathers. This study showed no correlation between paternal exposure to microwave and mongoloid offsprings. Thus the original finding was a false-positive.

With the present lack of identifiable disease states which result from low level exposure in a relative short period of time, it is considered to be more cost-effective to utilize available funds for laboratory research to adequately determine and characterize biological effects prior to attempting epidemiological studies.

Both the Army and Air Force have conducted epidemiologic studies evaluating cataract incidence in microwave workers. To my knowledge both of these studies failed to show a higher incidence of cataracts in the exposed groups. Possible criticism of these studies includes inadequate time of follow-ups, particularly if the disease requires a long development time. Although this point was partially compensated for by having some workers who had many years of microwave exposure included at the start of the studies.

Presently the Medical Follow-Up Agency of the National Research Council is completing a retrospective study of naval personnel thought to have been exposed to radar, together with a control group. Again, to my knowledge no correlation has been found to relate microwave with cataracts. But this study also suffers from some defects, such as: the actual exposure or non-exposure of personnel in the study is unknown, but only estimated based on the man's job classification.

The Naval Health Research Laboratory in San Diego has computer access to naval hospital and personnel records. Last year at my request they ran a short program to identify the number of naval personnel discharged from naval hospitals with the diagnosis of "cataracts." This diagnosis was related to "age" and job classification. It was found that the diagnosis of cataracts was present in all age groups and the incidence increases with age. There were about 9 cases of cataracts per 100,000 persons at age 18–19, and increases to over 150 cases per 100,000 persons by age 50. When the incidence was looked at by occupation, the highest incidences were reported in Hospital Corpsmen and the construction workers. While the lowest incidence was in the electronic personnel where one normally expects the highest incidence of exposure to microwaves and electromagnetic radiation in general.

In providing some insight to where we go from here, I have outlined the direction of the Navy research program. It will conduct some research in basic mechanisms of interaction particularly trying to determine the effects of cellular membranes. The remaining research will be directed toward determining threshold levels for specific effects in the five areas discussed before. These threshold levels will be determined for various frequencies and for long-term exposures. We also plan some work toward better definition of the factors needed to extrapolate animal data to man.

As to the needs for the entire non-ionizing electromagnetic radiation area, the original research recommendations made by ERMAC in 1971 are as relevant today as they were then. Recently, ERMAC has again completed another series of extensive reviews of all the federal agencies' programs in this area and is preparing to update the research guidelines in light of current knowledge and the present agencies' programs.

As noted before, the DOD Tri-Service panel has developed a long-term program outlining the overall objectives required to meet DOD requirements. In addition to the ERMAC and DOD documents on program needs, many other groups and several individuals have extensively reviewed the area and published papers on research recommendations. These include, the C–95 Committee of the American National Standards Institute documents on research needs which they feel are required to provide adequate evaluation for the development and establishment of exposure standards. The National Council on Radiation Protection and Measurements has two committees reviewing this area. The European Office of the World Health Organization has recently published a report on research needs.

In 1973 an international symposium was held in Warsaw, Poland, with both Western and Eastern scientists in attendance. During this symposium both the Western and Eastern scientists met in various groups and developed recommendations for future research needs which have been published in the proceedings of the symposium. Recently, the International Radiation Protection Association published an "Overview on Non-Ionizing Radiation," and has proposed to establish an International Commission on Protection Against Non-Ionizing Radiation (ICPNIR) which would address itself to the development of the protection of workers and populations against non-ionizing electromagnetic radiation.

When one reviews all of these various research recommendations, one is struck by the similarities. Some may vary slightly in their details or particular emphasis, but they all contain the same fundamental recommendations. This is not surprising, since it is obvious to anyone working in the field and familiar with the current literature, what is and is not known. There seem to be more people reviewing the problem and making recommendations than there are people doing the research.

In conclusion, Mr. Chairman, the Navy feels it has a responsive program directed toward the solution of the Navy problems. This program is also well-coordinated with the other federal agencies through OTP. There still is a need for additional funding to acquire the knowledge within a reasonable period of time.

I will be happy to try to answer any questions you or the committee may wish to ask. Thank you.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND THE ANSWERS OF CAPTAIN TYLER

Question 1. Is it not true that at least on one occasion the Navy lowered the maximum intensity of radiation which would be emitted from Project Seafarer? If, as you say in your testimony, "No adverse biological effect has been substantiated . . ." what prompted you to lower the figure?

Answer. It is my understanding from reviewing the records and discussions with personnel in the Seafarer Project Office, Naval Electronic Systems Command (NAVELEX), that in the early Seventies when the Navy was reviewing alternate sites to Wisconsin, two intensities were considered—.14 V/m for Western sites where the ground conductivity was not as good as that in Wisconsin, and the current .07 V/m over the antenna for areas over the Laurentian shield. Because of the cost and engineering problems in developing two systems to meet these two intensities, the Seafarer Project Manager at that time decided they would develop one system and that would be the one that met the .07 V/m criteria. The question of possible biological effects did not enter into the decision. It should be noted that the National Academy of Sciences (NAS) report has been released which found no serious adverse biological effects although they did question the engineering aspects of the grounding system as a possible shock hazard. This is being addressed by the engineers. A copy of the NAS report has been forwarded to your committee.

Question 2. You referred to experiments which indicated that exposure to microwave fields caused aversive behavior in rats. Have such effects been observed in humans, primates, or large mammals? Please provide citations to references where appropriate.

Answer. To my knowledge no experiments have been done or observations made of aversive behavior in humans, primates or large animals. The research reported was done with rats and mice. Rat research was done by Allan H. Frey, whose results are included in his article, "Neural Function and Behavior: Defining the Relationship," in: Annals of the New York Academy of Sciences, Vol. 247, Tyler, P.E. (Ed.), page 433, February 1975. A similar report was given by Edward L. Hunt at the USNC/URSI Annual Meeting, Boulder, Colorado, October 20–23, 1975. To date, Mr. Hunt's paper has not been published. A third report with mice was given at the same conference by John C. Monahan which has been published in Biological Effects of Electromagnetic Waves, Vol. I, HEW Publication HEW (FDA) 77–8810, December 1976.

It should be pointed out that "aversive" was the term used by some of the investigators which under the experimental conditions may or may not be proper. One could have used the word "preference." For example, it was found that rats placed in a shuttle box (a box with two compartments, one compartment was exposed to microwave while the other side was shielded) spent more time in the shielded side during exposure periods than rats under sham conditions. While the studies indicate that somehow the rats can perceive some changes in the microwave irradiated chamber and prefer to be in the other chamber for a greater portion of the experiment, the fact that the rats did spend some part of their time in the irradiated side indicates that irradiation is not totally aversive if they went into the chamber. In this case it doesn't take long for them to completely avoid the shock hazard side.

Question 3. During the hearings it was noted that changes in the Seafarer field seemed to affect bird migration patterns, while a steady time independent field did not. Does this imply that in some cases the field intensity is less important in producing bioeffects than its rate of change?

Answer. The studies with Seafarer fields and bird migration are still continuing. If it is verified that the migratory patterns are only altered during the period of time the field is changing (when it is being turned on or off), then certainly one hypothesis could be that the rate of change is producing the effect. It is known that several biological sensory systems are more responsive to rates of change than to a steady state.

Question 4. In discussing the effects of chronic long term exposure to microwaves, you referred to a study being done at the University of Washington which you seem to feel is inadequate, because you are "not sure that all of the critical parameters are currently being investigated." What specifically are the critical parameters being ignored? Who is conducting this study? Is the Navy funding this study?

Answer. The major objection to the University of Washington study is the use of 2450 MHz as the exposure frequency and to the exposure in the near field versus the use of far field exposures.

While 2450 MHz is a common frequency it is probably not the most critical frequency for biological interaction with the lens. Thus established thresholds for 2450 MHz may, in fact, be higher than for other frequencies. Present research indicates that the most critical frequency is somewhere between 5 and 10 Gigahertz, probably around 7 Gigahertz (7000 Megahertz). To be able to provide better extrapolation to man, far field exposures should be used as this is the type of exposure most people will encounter. For definitive long-term studies the animal model should have an eye structure more closely related to man than the rabbit. Although rabbit studies are still useful and valuable for short term efforts, such as evaluation of various temperature probes, energy distribution, evaluation of continuous waves versus pulsed systems, etc.

The present study is being conducted in Dr. William Guy's laboratory at the University of Washington, the principal investigator is Dr. P. O. Kramer. The Office of Naval Research is providing funds for this study.

Question 5. You spoke to the Committee about a primate cataract study which was discontinued because it was considered to be poor research. Please explain in more detail the shortcomings of that research project and the procedures followed in terminating it.

Answer. In September 1970, I was assigned the responsibility for the Bureau of Medicine and Surgery's program in microwave radiation. In October 1970, I made a site visit to Hawaii where the research was being conducted. Upon review I noted the following shortcomings:

(*a*) Lack of adequate expertise conducting the research on a day-to-day basis.

(*b*) Lack of adequate research records.

(*c*) Maintenance of animals did not meet minimum standards for animal care.

(*d*) There was total lack of sham exposures for proported control animals.

(*e*) Animals were maintained in the exposure field by use of metal chains around their necks.

(*f*) The field dosimetry was very poor.

(*g*) There was no provision made to insure that the eyes of the animals were receiving a uniform irradiation. The monkeys were free to move in the field. In fact, those chained in the first row (highest exposure) spent most of their time facing away from the radar and looking at the monkeys behind them. Thus the eyes were receiving a lesser exposure than monkeys supposedly exposed to small field intensities.

(*h*) The stand for the monkeys was a flexible pipe which the monkeys could swing, thus moving themselves in and out of the field. With this wide movement of the monkeys, their exposure dose was impossible to obtain with any degree of accuracy.

The above represent some of the major defects in the program. The research program was in its second year but was on a single year contract which would end in April 1971. Upon my return in October 1970, the Bureau of Medicine and Surgery notified the Office of Naval Research (contracting agency) that we did not plan to continue to support this research project after the present contract expired in April 1971. Because of an administrative error within ONR, the contractor was not notified until February 1971, to which he complained of the short notice. He also complained to various officials about the Bureau's not continuing the research program. Because of the delay in the notification by ONR, the Bureau of Medicine and Surgery provided additional funds and extended his contract to 30 June 1971 to insure an orderly phase down of the program. Because of his general complaint about stopping the research, the Assistant Secretary of the Navy (Research and Development) appointed an outside committee to review the program (a copy of their report is enclosed together with the memorandum from the ASN(R&D) to the Bureau of Medicine and Surgery (enclosures 1 and 2). Their findings concurred with the assessment that the research was not worth continuing. Thus a new contract was not approved.

Question 6. You mentioned that some studies have shown the delayed onset of an effect, such as change in white blood cell count, following microwave irradiation. Could you please describe the studies in which this happened? Did any of them involve human subjects?

Answer. The study referred to in my testimony concerned immunological changes in white blood cells. Enclosure 3 describes the objective, approach, and findings. The significant increase in the frequency of a subpopulation of B lymphoid cells bearing a receptor for complement (CR+) did not appear until about day 5 and was pronounced at seven days after exposure. This study was with mice and did not involve human subjects.

Question 7. You stated that "many investigators have reported various behavioral changes using a wide variety of exposure parameters and conditions". Please list and describe briefly these changes and the conditions under which they occur. Do these corroborate the Eastern European occupational studies?

Answer. The following brief descriptions of some behavioral experiments should serve to illustrate the variety of behavioral parameters, exposure parameters and even exposure conditions used by investigators in this field. Unless otherwise stated, irradiation was conducted in some approximation of a far field environment in an anechoic chamber. The results are also varied. All of the five studies listed below were reported within the last two years. Some major parameters have been tabulated on the next page.

Thomas, *et al.*, examined the effects of 2.86 and 9.6 GHz pulsed microwaves on the behavior of albino rats. Significant alterations were found in the ongoing performance on multiple reinforcement schedules following irradiation at either frequency at levels as low as 5 mW/cm^2.

Gillard, *et al.*, in France, has reported that irradiation of rats at levels as low as 0.7 mW/cm^2 causes changes in spontaneous behavior. These investigators used pulsed microwave irradiation at 9.4 GHz. In control animals locomotor activity, emotivity, and vigilance decrease during the test and exploratory activity increased. However, in irradiated animals exploratory activity increased. However, in irradiated animals exploratory activity increased more slowly, vigilance at first increased then decreased and locomotor activity is unchanged by the procedure.

deLorge has found that vigilance performance of a rhesus monkey was not affected unless power levels in excess of 50–60 mW/cm^2 were used.

Monahan and Ho exposed mice to continuous wave irradiation at 2.45 GHz. They observed aversive behavior at average absorption levels of 28 mW/gm. It should be noted that this experiment was conducted in a wave guide.

Sanza and deLorge found that not until they were exposed to 37.5 mW/cm^2 did rats show a consistent decrement on a fixed interval level press task.

As can be seen, a wide variety of experimental conditions have been used and various results have been reported. None of these findings corroborate Eastern European occupational findings, which for the most part have been subjective behavioral reports of the workers and not objective behavioral changes as noted in the above studies.

Investigator	Animal	Frequency	Wave form	Exposure time	Intensities (power levels)	Test used
Thomas	Albino rat	2.86 GHz, 9.6 GHz.	Pulsed 1 μsec, 500 Hz.	30 min	5, 10, 15, 20 mW/cm^2.	Multiple reinforcement schedules.
deLorge	Squirrel monkeys.	2.45 GHz	CW with 120 Hz modulation.	1 hr	4, 16, 32 42, 52, 62, 72 mW/cm^2.	Vigilance behavior.
Gillard	White rats	9.4 GHz	Pulsed 0.15 μsec. 2,000 Hz.	2 weeks	0.7 mW/cm^2	Open field trials.
Monahan	CFI mice	2.45 GHz	CW	15 min	0.4, 0.8, 1.6, 2.4, 3.2, 4, 4.8 W forward power.	Avoidance behavior.
Sanza	Sprague Dawley rats.	2.45 GHz	CW with 120 Hz modulation.	Not given	8.8, 18.4,37.5 mW/cm^2.	Fixed interval behavior.

Question 8. Please describe the experiments investigating responses to electromagnetic radiation at the Naval Aerospace Medical Laboratory in Pensacola. Please include a description of the experiment's design and any preliminary findings.

Answer. The enclosed Research Resumes, enclosure 4–8, briefly describe the current research being conducted at the Naval Aerospace Research Laboratory, Pensacola. In addition, enclosure 9 is a detailed protocol of primate chronic exposure to electric and magnetic fields in support of Project Seafarer. The preliminary analysis of this experiment has shown no apparent differences between the experimental and control groups. This data was forwarded to the NAS committee for their review. In addition, the Principal Investigator, Dr. J. Grissett, made an oral presentation to the committee. The final analysis of all the data is not yet complete. Presently, the data is being analyzed by sex group.

Question 9. The *New Yorker* articles on microwaves alleged that human volunteers were exposed at Pensacola and the results indicated elevated blood serum triglyceride levels. Additionally, it has been alleged that the results of these studies were suppressed for an inordinate length of time. Please comment.

Answer. A preliminary study was conducted at NAMRL using volunteer human subjects during 1972. The study consisted of 10 experimental and 5 control sessions where the subjects were confined for periods of up to 7 days. Experimental subjects were exposed to a low intensity magnetic field of 1 Gauss for periods of up to 24 hours.

There was a rise in triglycerides noted in the experiment and commented on by the investigator as follows:

"No effects were seen that could be definitely linked with the magnetic field; however, serum triglycerides in most subjects appeared to be affected by some factor or combination of factors associated with the experimental protocol. Serum triglycerides in 9 of the 10 exposed subjects reached a maximum value 24 to 48 hours after the ELF field exposure. Similar trends were not seen in any of the 5 control subjects. The number of subjects is too small, however, to exclude statistically other factors such as psychophysiological reactions to forced changes in personal living habits, modified activity, restricted diet, and confinement. A final conclusion must await further experiments and the establishment of a relationship between field strength nad physiological effects, as well as establishment of a threshold for the effects."

This data together with all the other reports were reviewed by the NAS committee and their comments have been enclosed (enclosure 10).

The study was done during calendar year 1972 and the report published in July 1973 as a NAMRL Technical Report No. 180. As soon as it was published it was widely available through the National Technical Information Service. I do not consider the study being done in 1972 and a report being published in July 1973 a suppression of the data for an inordinate length of time.

I am not aware that Mr. Brodeur made any attempt to contact the Navy or request from the Navy any information concerning his allegations. Certainly Mr. Brodeur is entitled to his opinions, but personally, I think it prudent to try and obtain all the facts possible from all available sources before something appears in print.

Question 10. On Sunday, August 7, 1977, a *Washington Post* article on "psychic spying" discussed a Naval research project which concerned ELF and mind control. What happened to this research project? Are similar projects being conducted now? Why weren't such projects, however bogus, disclosed to the Committee?

Answer. I was first aware of such projects upon reading the same article in the Washington Post. The two projects discussed in the article were supported by the Naval Electronics Systems Command (NAVELEX). It is my understanding from discussions with personnel in the Office of the Assistant Secretary of the Navy (Research, Systems and Engineering) (OASN(RS&E)) that the first project was a contract with Stanford Research Institute. When this effort became known in the OASN(RS&E), NAVELEX was directed to close out the project and not to conduct any further research in the area of "psychic" phenomenum.

It is also my understanding that Dr. Curry, former Director of Defense Research and Engineering, also issued a memorandum directing all three services not to conduct "psychic" research. I have been informed that OASN(RS&E) and the Commander, NAVELEX, were not aware of the second study being conducted at the Naval Ocean Systems Center (formerly Naval Electronics Laboratory Center). Upon release of the article in the Washington Post on 7 August, the project was cancelled on 9 August and an investigation is underway to determine why it was started in the first place.

The two studies had nothing to do with electromagnetic radiation. EMR was not utilized in the studies. In simple terms, one man in a room would look at a series of numbers and another man in a second room would try and "guess" what number the first person was observing and thinking about at specific times. The psychic transference of one's thoughts. The use of the acronym ELF is somewhat misleading. I assume that what the author was talking about is the hypothesis put forward by some people to explain "psychic" phenomenum. This hypothesis theorizes that since we know that the brain generates very low intensity "electromagnetic" waves, which can be measured by an electroencephalogram (EEG); these waves are in the ELF region, 0–100 Hertz; man somehow can control these emissions and thus transfer information from one person to another person directly by these "ELF waves".

This concept has nothing to do with man-made electromagnetic fields and their interactions with biological systems. Being unaware of the projects, and the fact that they were not concerned with man-made, in the engineering sense, electromagnetic fields, are the reasons for not discussing them with the Committee. There certainly was no intent to withhold information.

Question 11. Please amplify your comments on the role played by OSHA in response to the Boeing Company's petition for an exposure standard to the electromagnetic pulse project. Please provide the Committee your response to Mr. Brodeur's description of this problem in the New York articles. (See Microwaves II, pp. 73 et seq.)

Answer. To my knowledge, OSHA, in response to the Boeing Company's petition, published in the Federal Register a notice of the petition and requested information for evaluation in considering Boeing's petition. I am not aware of all the information that was submitted to OSHA, but I know of studies conducted by the Armed Forces Radiobiology Research Institute where rodents were exposed to EMP almost continuously for up to 94 weeks. Detailed studies revealed no abnormalities nor an increase incidence of Leukemia or other tumors. Following OSHA's consideration of the available data they ruled that such a standard was not warranted at that time.

Commenting on Mr. Brodeur's description of this problem is very difficult. Not being personally involved or having first hand knowledge of the incidents discussed, I am not sure that he pursued all avenues open to him to acquire the facts from all the parties concerned.

It appears that he may have started from a basic premise and then selected and developed the "facts" to prove his point. He reports that seven people "involved" developed cancer—3 Leukemia, 1 skin cancer, 1 bladder cancer, and 2 cancers-type unknown. There are also several types of blood cell cancers all lumped under the general term Leukemia.

Medical science knows that there are probably many ways cancer can be induced and in fact many different potential carcinogens have been identified through laboratory research. On the other hand, nonionizing radiation has yet to be shown carcinogenic by laboratory experiments. For one to make the broad assumption that these particular people were not exposed to any other potential carcinogenic agents but that their various cancers were due to their EMP exposure is literary license and not science.

Question 12. During the hearing you stated that the incidence of pancreatic cancer among the TACAN repairmen was anomalous, but you implied it was of no further relevance to this inquiry. Please provide the Committee with your reactions to the charges raised by Mr. Brodeur in the New Yorker articles that the military's and NIOSH response to these reports was inadequate.

Answer. There have been many actions taken by both NIOSH and the Bureau of Medicine and Surgery including meetings of all interested parties, since the one meeting reported by Mr. Brodeur. These additional meetings have been held both prior to his published article and since its publication. Several TACAN repair facilities have been surveyed. NIOSH and Navy reports are enclosed (enclosures 11 and 12). Again, to my knowledge Mr. Brodeur made no attempts to contact or follow-up the issue with responsible Navy personnel.

I do not think the investigation has been inadequate, it may have progressed slower than some people would have liked, but it seems to be a fact of life that at times the wheels of our bureaucracy grind very slowly.

In my statement, I inferred that it may be an anomalous finding that two people working together show up with the same disease. I have since been informally told that not only did the two men work together, but they car pooled together, lived close by, and were personal friends who did many activities together—which further complicates any simple work relationship.

[ENCLOSURE 1]

THE RAND CORPORATION,
Washington, D.C., August 16, 1971.

Subject: Review of Contract N00014–69–C–0358, "Radio-Frequency Hazards," Principal Investigator: Dr. Milton M. Zaret.

Mr. HARRY SONNEMANN,
Special Assistant to the Assistant Secretary of the Navy (R. & D.), Department of the Navy, The Pentagon, Washington, D.C.

DEAR HARRY: An ad-hoc committee consisting of the undersigned was established at your request to review the above contract: in particular, "to establish whether the procedures being employed to investigate the potential hazard of low-level microwave radiation are adequate. . . . The issue is whether the techniques employed will result in scientifically credible data from which pertinent clues with respect to the formation of cataracts can be extracted with assurance that the data base is valid." This is a summary of the committee's findings.

It is important to recognize at the outset that this contract consists of two separate studies. The first study is being conducted at the Zaret Foundation primate facility on Laulaunn Island in Pearl Harbor and involves Dr. M. M. Zaret (who was not resident at the site) and Dr. W. F. Lyons assisted by Miss S. B. Robinson. This experiment is directed primarily toward long-term, low-level chronic exposure of primates. The second study is being conducted at the Polytechnic Institute of Brooklyn by Professor Saul W. Rosenthal and Dr. Ira T. Kaplan (of the Zaret Foundation) assisted by Mr. Leo Birenbaum (P.I.B.) with consultation from Dr. Zaret. This consists of laboratory measurements of heart rate, respiration rate, and sub-cutaneous temperature of rabbits exposed to CW 2450 MHz microwave energy. According to Dr. Zaret's statement, approximately 10 percent of the funds were expended in the second study.

It is clear that the intent of your letter primarily was to review the Hawaii study.

I. GENERAL FINDINGS

It is the general opinion of the committee that:

A. Long-term, low-level exposure of primates to microwave is a worthwhile and necessary experimental effort.

B. The principal study in concept and execution has not utilized adequate techniques or proper scientific methodology and will not result in scientifically credible data. The performance to date is such that it is doubtful whether valid research on this problem would be performed in the future by the same personnel using the same or another approach.

C. It is concluded that the second experiment at Brooklyn has employed adequate techniques and can supply useful contributions to the scientific literature. Continued work could lead to additional useful research.

D. It must be pointed out that the Navy shares responsibility for the poor showing in the principal experimental effort. According to Dr. Zaret, and evidence from the course of the experiment, the Navy clearly did not supply a source of adequate intensity to properly carry out the experiment, and it is the opinion of the committee that inept and casual management was demonstrated by the Navy organization involved in controlling the course of the study. Further, both Dr. Zaret and the Navy organizations involved did not adequately either estimate the cost or the planning necessary for proper utilization of a large number of expensive animals for this type of experiment. Nor was there adequate utilization of the basic experimental capability for other physiological, biochemical or behavioral measurements. It is also questionable whether data on only two animals per point could provide credible extrapolation to man in a matter of this level of significance. In summary, the experiment was badly underestimated in both technical complexity and funding.

The specific findings of the committee in the principal experiment follow:

I. EXPERIMENTAL PROCEDURES

These were generally inadequate for studying the effects of low-level radiation in animals.

A. Animal Handling:

1. Animal care was not in accordance with good laboratory practice.

2. Animal restraint procedures during exposures were poor. Examination of the data log indicated that of five monkeys' deaths, three were certainly due to strangulation resulting from poor experimental design of the restraint system. Leaving animals on their perches overnight is poor practice and was probably contributory to some of the deaths.

3. No satisfactory evidence was presented of provision for routine pre- and post-experimental examination of the animals.

B. Microwave Calibration and Measurement Techniques:

1. While the instruments used were calibrated by Dr. Rosenthal (P.I.B.), he never himself visited the site nor participated in on-site measurements.

2. No satisfactory measurements were presented for the exposure fields. The only data shown seemed vague, casual and amateurish.

3. There was no measurement or logging of the radiation data during exposure periods.

4. The problem of artifacts in measuring microwave fields in the presence of metallic collars, support pipes and the presence of dielectrics of unknown properties was not analyzed or documented. There is no evidence that variations due to the presence or absence of the animals in various constraining systems were measured or recorded.

C. Observations were poorly recorded. The data books gave no details of factual observations. Pre-experimental, experimental, and post-experimental records on the exposed and controlled animals were incomplete. Necropsy records did not indicate gross or microscopic findings.

D. There is no evidence of any adequate biochemical or physiological control procedures of even a routine nature that should be intrinsic to an experiment of this type.

II. SCIENTIFIC MANAGEMENT AND PLANNING

A. The microwave field intensity levels used were a factor of 5 less than the proposed level, and as such did not overlap exposure intensity levels known to produce cataracts. As mentioned above, the Navy shared responsibility in not providing equipment adequate for performing the intended experiment.

B. There is a substantial question as to whether Dr. Lyons and Miss Robinson had adequate training or experience to carry out the microwave experiments without considerably more supervision than indicated. Notations in the log appear to be those of inexperienced, non-technically trained individuals.

C. No information was presented of adequate laboratory or other support facilities available to a program of this magnitude.

D. It is difficult to understand why radiations ceased February 1971 when personnel were still on the site, and the primate colony, equipment, and site were available, particularly after funding was made available until June.

E. It did not appear to the committee that Dr. Zaret was adequately familiar with, or had exercised a careful review function on, the data during or since the exposure.

III. RESULTS

At the conclusion of the radiation, only one primate had over 1,000 hours at 20 mw/cm^2 and only one other had 1,000 hours at 10 mw/cm^2. No observations of cataracts were reported. They were not necessarily anticipated for these exposures.

No material has been presented to date which is scientifically credible and which could result in scientific publication. In fact, it appears that no technical report of any degree of detail has been presented relative to work on this portion of the contract.

We wish to express our appreciation for the opportunity to assist the Department of the Navy in this matter. Please let us know if any additional information is required.

Sincerely,

SAMUEL KOSLOV,
The Rand Corporation, Chairman.
WILLIAM A. MILLS, Ph. D.,
Environmental Protection Agency.
DAVID D. DONALDSON, M.D.,
Harvard University.
SOL M. MICHAELSON, D.V.M.,
University of Rochester.
JOHN M. OSEPCHUK,
Raytheon Company.

COMMITTEE MEMBERS

Dr. David D. Donaldson, Massachusetts Eye and Ear Infirmary, 275 Charles Street, Boston, Mass. 02115, 617/532-7900.

Dr. Sol Michaelson, Department of Radiation Biology and Biophysics, the University of Rochester, Rochester, N.Y. 14628, 716/275-3811.

Dr. William Mills, Environmental Protection Agency, 12720 Twinbrook Parkway, Rockville, Md. 20852, 301/443-3438.

Dr. John Osepchuk, the Raytheon Company, 28 Seyon Street, Waltham, Mass. 02154, 617/899-3811.

Dr. Samuel Koslov, the Rand Corporation, 2100 M Street, NW., Washington, D.C. 20037, 202/296-5000.

[ENCLOSURE 2]

THE ASSISTANT SECRETARY OF THE NAVY,
RESEARCH AND DEVELOPMENT,
Washington, D.C., July 22, 1971.

MEMORANDUM FOR REAR ADMIRAL FAUCETT, ASSISTANT CHIEF FOR RESEARCH AND MILITARY MEDICAL SPECIALITIES, BUREAU OF MEDICINE AND SURGERY

Subj.: ONR Contract N00014-69-C-0358 With Zaret Foundation, Review of.

At my request, Dr. Samuel Koslov of the Rand Corporation constituted a small review group to evaluate the subject contract, particularly to establish whether the procedures being employed to investigate the potential hazard of low level microwave radiation are adequate to result in scientifically credible data from which pertinent clues with respect to the formation of cataracts can be extracted with assurance that the data is valid.

The group was supplied with all pertinent information prior to a meeting with Dr. Zaret on 25 June 1971. The committee of five consisted of the following members:

Dr. Samuel Koslov, the Rand Corporation Research Council, Chairman.

Dr. John M. Osepchuk, Manager Electron Beam Devices, Raytheon Company Research Division.

Dr. William A. Mills, Acting Chief for Radiation Research, Environmental Protection Agency, Office of Research and Monitoring.

Professor David D. Donaldson, Associate Professor of Ophthalmology, Harvard University Medical School, Howe Laboratory of Opthalmology.

Professor Sol M. Michaelson, Associate Professor, University of Rochester, School of Medicine and Dentistry.

Dr. Koslov has informed me that it was the unanimous opinion of the committee that the research conducted in Hawaii has been generally poor. The experimental procedures were judged to be inadequate to draw valid conclusions on the potential hazards of low level microwave radiation. The maximum power level capability of the SPS-10 Radar is too low to obtain acute explosure data. Animal care and facilities as well as records on their condition were extremely poor. Calibration procedures were inadequate. The log books and documented observations are sketchy. Deaths of five additional monkeys apparently from causes not connected with exposure to radiation were not reported. The committee was also informed by Dr. Zaret that he ceased all radiation exposures in February.

The work carried out by the Polytechnic Institute of Brooklyn by Doctors Kaplan and Rosenthal which represents less than 10 percent of the work was well done and has scientific merit.

In view of these findings I concur in your recommendation to terminate this contract. Consideration should be given to picking up the Polytechnic Institute of Brooklyn work directly with Professor Rosenthal.

ROBERT A. FROSCH.

[Enclosure 3]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

2. Project
☒ New ☐ Revised
☐ Proposed ☐ Completed
☐ Continued ☐ Terminated

1. Title: Effect of Low-Dose Microwaves on the Immune Response of Mice

3. Dept./Agency:
U.S. Navy N-91

4. Funding Component:
Naval Medical R&D Command
a. Jointly Funded With:

5. Program Contact: CAPT P.E. Tyler, MC, USN
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:
Naval Medical Research Institute
a. Principal Investigator:
K. W. Sell, M.D., Ph.D.

7. Start Date: December 1976

8. Estimated Completion Date: Continuing

9. Frequency(ies): 2.45 GHz CW & Pulsed

10. Exposure Range: 1 - 20 mW/gm

11. Resources:

Year	a. Manyears	b. Funds
CFY-1: 1976	1	26
Current: 1977	1	66
CFY + 1:		
CFY + 2:		

Project Summary: 12. Objective, 13. Approach

12. Objective. The objective is to study the effects of long-term, low-dose microwave exposure on the immune response of laboratory animals as experimental models.

13. Approach. Mice will be irradiated with continuous or pulsed 2450 MHz microwave radiation to a total single dose of 10 mW/g tissue one or more times during 1 or 2 weeks. The same number (usually 9) will serve as a control. The bone marrow and peripheral blood picture of normal and microwave irradiated mice will be determined using routine methods. Spontaneous transformation of peripheral blood white cells in 6-hour cultures and spleen cells in 6-, 72-hour, and 5-day cultures will be evaluated by incorporation of tritiated thymidine, uridine, and leucine. Moreover, mitogen-induced transformation tests will be performed with spleen cells using phytohemagglutinin, Concanavalin A, pokeweed mitogen, lipopolysaccharide B of Escheria coli, poly-I, and poly-C, as well as mixed lymphocyte culture tests according to methods of Strong et al. and Thurman et al. Additionally, spleen cells from experimental animals will be evaluated for presence of surface markers; i.e., Fc receptor, complement receptor for quantitation of populations of B cells and theta antigen for quantitation of T cells. These experiments will shed light on the effec of low-dose microwaves on the immune response.

Title: Effect of Low Dose Microwaves on the Immune Response of Mice

14. Progress: CBA/J male adult mice were exposed to 2450 MHz microwaves (Amplitude modu ated 12 Hz) at a forward power 0.6 watts for 30 minutes in an environmentally controlled waveguide facility. The absorbed dose rate was computed from measurements of forward, reflected, and transmitted power and was about 14 mW/g body weight of the animal for each exposure. The experiments were carried out with two groups of mice. One group received single exposure for 30 minutes, the other group a total of three exposures of 30 minutes each at three day intervals. Sham exposed animals served as controls.

A single exposure to microwaves in such conditions produced a significant increase i the frequency of a subpopulation of B lymphoid cells bearing a receptor for complement (CR^+). Triple exposures not only enhanced this effect, but also significantly increased the total frequency of Ig+B cells in spleens of exposed mice. The effect was pronounced seven days after expousre and was independent of cell proliferation since the total numbe of spleen cells and theincorporation of ^{3}H-TdR (DNA-precursor), ^{3}H-Uridine (RNA-precursor and ^{3}H-Leucine (protein precursor) by spleen bone marrow, and peripheral blood lymphoid cells of the exposed mice remained unchanged. This effect could not be related to the arrest of further maturation of B cells in CR^+ stage, since seven days after a single expo sure the number of cells spontaneously forming IgM antibody also increased as evaluated by the plaque assay. Moreover, the functional immune capacity of these mice was evaluate by the response of their spleen cells *in vitro* to B cell-specific mitogens: dextran sulphate lipopolysaccharide, poly I.D., and PPD-turberculin. While there was no significant increase in their ability to respond to dextran sulphate (which stimulates neonatal B cells), there was a signficant increase in their ability to respond to the other B cell mitogens used.

The proportion of T lymphoid cells (theta-positive) remained unaltered similarly as their functional capacity as evaluated by response of spleen cells *in vitro* to the T cell specific mitogens-phytohemagglutinin and concanavalin A and to allogeneic stimulator cells in mixed lymphocyte cultures.

Groups of CBA/J male adult mice were injected on day "0" with 0.5 ml of saline, or 0.2 ml of T lymphoid cell dependent antigen (i.e. requiring the cooperation of T cells for the production of antibody) -- sheep red blood cells (SRBC) or 100 μg of synthetic T cell independent antigen (i.e. B cells produce antibody without cooperation with T cells) -- DNP-lysine-Ficoll. On days 1, 2, and 3 the experimental groups consisting of four animals each were exposed to 2450 MHz microwaves. Controls consisted of mice which were sham-exposed. Exposures were performed in an environmentally controlled waveguide facility with a forward power of 0.6 watts to the average absorbed dose rate about 12 mW/g body weight for each exposure. On day 4 mice were sacrificed and their spleen cells were assayed for antibody by the modification of the direct plaque assay of Jerne. Cells from SRBC immunized animals were assayed using SRBC as indicator cells, while cells from DNP-lys-Ficoll immunized mice were plaqued against SRBC coated with appropriate antigen determinant - trinitrobenzene sulfonic acid. Cells from saline injected animals were assayed against both these indicators.

While the number of IgM antibody secreting cells increased in non-immunized (saline) microwave-exposed mice as compared to non-immunized sham animals, the ability to form specific antibody against both T-dependent and T-independent antigen decreased in microwave exposed animals. The difference was, however, statistically significant only in the case of their response to the T-independent antigen.

Title: Effect of Low Dose Microwaves on the Immune Response of Mice

These results suggest that while microwaves stimulate non-specific reactivity of B lymphoid cells, they simultaneously decrease the number of antigen reactive cells specifi for both thymus dependent and independent antigens. These exposure conditions of microwaves _in vivo_ seems to be weakly immunosuppressive. Further studies on the mechanism of this reaction are currently in progress.

Publications:

W. Wiktor-Jedrzejczak, A. Ahmed, P. Czerski, W.M. Leach, & K.W. Sell. "Microwaves (2450 MHz) stimulate maturation of B lymphoid cells in spleens", In: USNC/URSI Annua Meeting, Abstracts, p. 20, Amherst, Mass., October 1976. To be published in _Radio Science_.

W. Wiktor-Jedrzejczak, A. Ahmed, P. Czerski, W.M. Lead, & K.W. Sell. "The effect of microwaves (2450 MHz) on the response of mice to T lymphoid cell dependent and T lymphoid cell independent antigens: Preliminary results", Idem.

[Enclosure 4]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title: Biological Effects of Localized E- and H-Fields in the Standing Microwave Field

MR041.08.01-0002

3. Dept./Agency:
U.S. Navy N-70

4. Funding Component:
Naval Medical R&D Command

a. Jointly Funded With:

5. Program Contact: P.E. Tyler, CAPT, MC, USN
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:
Naval Aerospace Medical Res Lab
Pensacola, Florida

a. Principal Investigator:
R. G. Olsen, Ph.D.

7. Start Date: July 1975

8. Estimated Completion Date: June 1980

9. Frequency(ies): 1 - 12 GHz

10. Exposure Range: < 30 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1: 1976	1.0	30K
Current: 1977	1.0	40K
CFY + 1:		
CFY + 2:		

Project Summary: 12. Objective, 13. Approach

12. Objective. Standing waves are found on board ship due to microwave reflections from metal walls and equipment. The effects of localized E- and H-fields on living objects will be investigated.

13. Approach. Electric (E) and magnetic (H) fields will be produced at different microwave frequencies by reflection of a traveling wave from a metal plate in an anechoic chamber. Measurements based on previous experience will provide information on the degree of local separation of the E- and H-components of the field. Samll organisms such as Tribolium pupae will be introduced into known parts of the field and the bioeffects (wing deformation in the imagio) determined. This series of experiments should provide some of the first information available on specific bio-effects of E- and H- fields at microwave frequencies.

14. Progress. The quipment for the study has been assembled and tested. Initial measurements of the standing wave configuration have shown that approximately 24 pupae can be irradiated simultaneously. Microwave dose rate measurements using phantom pupae have indicated that sufficient power is available to irradiate the pupae at the levels previously reported

PUBLICATIONS:
Olsen, R.G. "Insect Pupae Teratogenisis in a Standing Wave Irradiation System", In: USNC/URSI 1976 Annual Meeting, Abstracts p. 44, Amherst, Ma, October 1976. To be published in Radio Science.

[Enclosure 5]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title: Reflection and Diffraction Aspects of Biological Microwave Dosimetry
MF51.524.015-0036

3. Dept./Agency:
U.S. Navy N-69

4. Funding Component:
Naval Medical R&D Command
a. Jointly Funded With:

5. Program Contact: CAPT P.E. Tyler, MC, USN
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:

Naval Aerospace Medical
Research Laboratory
Pensacola, Florida

a. Principal Investigator:
R.G. Olsen, Ph.D.

7. Start Date: July 1975

8. Estimated Completion Date: June 1980

9. Frequency(ies): 1 - 12 GHz

10. Exposure Range: -1 - 30 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1: 1976	1.5	85K
Current: 1977	1.0	51K
CFY + 1:		
CFY + 2:		

Project Summary: 12. Objective, 13. Approach

12. Objective. Procedures are developed that will provide new insight into the energy absorbed from microwave fields by living systems. This information is necessary to make a valid estimation of the effects of microwave energy on naval personnel.

13. Approach. An electric energy density meter will be used to measure both the magnitud and direction of the vector electric field intensity in the region around the illuminated phantom model. A frequency of 1.0 GHz will be intially used to extend the results of previous experiments in this study. Emphasis will be placed on the economical acquisition of a three-dimensional distribution of vector E-field values representative of a closed surface completely surrounding the man-size model. The material used in the phantom will consist of a pliable, putty-like substance with gross microwave absorption properties adjusted to those of mammalian tissue.

14. Progress. The initial irradiation experiments of this study provided values of the scaler electric energy density in a two-dimensional plane at two elevations around a human subject and a mannequin coated with conductive paint. The results of these measurements have given a limited but very useful visualization of the manner in which an electromagnetic wave diffracts around an upright human subject. These results will be used as guide in the pursuit of quantitative estimates of the energy absorbed by the man-size phantom.

[Enclosure 6]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title: Biochemical Effects of Microwave Radiation

MF51.524.015-0034

3. Dept./Agency:
U.S. Navy N-68

4. Funding Component:
Naval Medical R&D Command
a. Jointly Funded With:

5. Program Contact: P.E. Tyler, CAPT, MC, USI
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:
Naval Aerospace Medical
Research Laboratory
Pensacola, Florida

a. Principal Investigator:
W. G. Lotz, Ph.D.

7. Start Date: July 1975

8. Estimated Completion Date: June 1980

9. Frequency(ies): 1 - 12.4 GHz

10. Exposure Range: 1 - 30 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1: 1976	1.6	87K
Current: 1977	1.6	96K
CFY + 1:		
CFY + 2:		

Project Summary: 12. Objective, 13. Approach

12. Objective. Biochemical studies are conducted in primates as an index of effects of microwave radiation on naval personnel.

13. Approach. Neuroendocrine parameters will be measured on rhesus monkeys for both acute and chronic exposure. For acute experiments the animals will be exposed for eight hours during a 24-hour period. Blood samples will be drawn by indwelling catheters at two-hour intervals. When the neuroendocrine response is determined for short exposure at high power levels, the frequency and pulse parameters will be used at moderate power levels for chroni exposure to determine the total physiological significance for responses at a particular se of field conditions.

14. Progress. A series of experiments were conducted to answer the following questions: (1) Do growth hormone changes correlate with colonic temperature changes in rats exposed to microwave radiation? (2) Can microwave-induced colonic temperature increases be negated by lowering the environmental temperature, and if so, will the growth hormone responses also b negated? In general the answers are yes, but the growth hormone changes were not completel negated to sham levels by lowering the environmental temperature. There remains the possib lity of a direct stimulatory effect on the neuroendocrine system, however, the data indicates that the majority of the effect was secondary to heat.

[Enclosure 7]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title: Behavioral Characteristics of Monkeys and Rats Irradiated with Microwaves
MF51.524.015-0037

3. Dept./Agency:
U.S. Navy N-66

4. Funding Component:
Naval Medical R&D Command
a. Jointly Funded With:

5. Program Contact: P.E. Tyler, CAPT, MC, USN
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:

Naval Aerospace Medical
Research Laboratory
Pensacola, FLORIDA

a. Principal Investigator:
J. O. deLorge, Ph.D.

7. Start Date: July 1975

8. Estimated Completion Date: June 1980

9. Frequency(ies): 2.4 & 6 GHz

10. Exposure Range: 8 - 72 mW/cm^2

11. Resources:

Year		a. Manyears	b. Funds
CFY-1:	1976	2.3	123K
Current:	1977	2.3	117K
CFY + 1:			
CFY + 2:			

Project Summary: 12. Objective, 13. Approach

12. Objective. Investigate the effects of low power density microwave radiation on animals by measuring ongoing operant behavior in monkeys and rats.

13. Approach. Rhesus monkeys, squirrel monkeys, and rats trained on various operant task will be exposed for prolonged durations to microwave radiation at low power levels, pulsed at selected frequencies. The animals, while working, will be exposed to vertically or horizontally polarized radiation at 2.4 and 6 GHz to demonstrate differential effects of polarization and frequency. The exposures will occur in essentially non-reflective restraint devices. In addition the animals, chosen for size differences, will perform on similar tasks and permit a comparative study of animal size and microwave parameters utilizing behavior as the dependent variable.

Title: Behavioral Characteristics of Monkeys and Rats Irradiated with Microwaves

14. Progress: Rhesus monkeys and white rats trained to respond on schedules of positive reinforcement were exposed to 2450 MHz microwaves in a far field. Power densities from 4-72 mW/cm^2 (rhesus) and 9-36 mW/cm^2 (rat) were used. Colonic temperature was obtained during exposure with the rhesus and after exposure on comparison groups of rats. Monkeys were reinforced on variable interval schedules and rats on fixed interval schedules while being exposed to microwaves. Only the highest power densities, 72 mW/cm^2 with monkeys and 36 mW/cm^2 with rats had consistent behavioral effects during one-hour exposures although body temperature began to increase at moderate power densities.

PUBLICATIONS:

Sanza, J.N. & deLorge, J.O. "Fixed Interval Behavior in Rats Exposed to Low Power Density Microwaves", In: USNC/URSI 1976 Annual Meeting Abstracts, p. 93, Amherst, MA, October 1976, Bioeffects Session. To be Published.

deLorge, J.O., Behavior and Temperature in Rhesus Monkeys Exposed to Low Level Microwave Irradiation. Naval Aerospace Medical Research Laboratory (NAMRL) Technical Report NAMRL-1222, Pensacola, FL, January 1976.

[Enclosure 8]

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 1 October 1976

1. Title: The Effects of Extremely Low Frequency (ELF) Radiation on Primates

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

3. Dept./Agency:
U.S. Navy N-17

4. Funding Component:
Naval Electronic Systems Command
a. Jointly Funded With:

5. Program Contact: P.E. Tyler, CAPT, MC, US
a. Title: Director, EMR Project Office
b. Phone Number: (202) 295-1140

6. Performing Organization and Address:
Naval Aerospace Medical
Research Laboratory
Pensacola, Florida

a. Principal Investigator:
J. D. Grissett, Ph.D.

7. Start Date: March 1970

8. Estimated Completion Date: Continuing

9. Frequency(ies): 75 Hz

10. Exposure Range: 1 - 2 Gauss
1 - 20 V/m

11. Resources:

Year	a. Manyears	b. Funds
CFY-1: 1976	6.2	668
Current: 1977	1.4	225
CFY + 1:		
CFY + 2:		

Project Summary: **12. Objective, 13. Approach**

12. Objective. Current Navy interest in electromagnetic radiation includes the extremely low frequency (ELF) region of the spectrum. An urgent need exists for information on the physiological and psychological effects of this radiation on man. The results of a systematic and controlled exposure of human volunteers in the laboratory, will contribute to alleviate the fears of an environmental radiation hazard to Navy personnel and to the general public.

13. Approach. Effects of chronic exposure are studied by exposing primates, *Macaca mulatta*, for a period of one year. A group of 30 experimental animals and 30 control animals are pair-matched by age, sex, weight, and medical history. The experimental animals are exposed ontinuously to magnetic and electric fields similar to those experienced by man in contact with the soil surface directly above a buried ELF antenna. Blood samples are drawn weekly for biochemical analysis. Physical examinations are given at six week intervals by a veterinarian. At the end of the one-year exposure period, part of the animals will be sacrificed for pathological examination. The remaining animals will be retained for a study on breeding behavior, fertility, prenatal development, neonatal physi logy, and postnatal growth while continuously exposed to ELF fields. Central nervous system development of offspring will be monitored by operant techniques with special emphasis on learning ability.

Title: The Effects of Extremely Low Frequency (ELF) Radiation on Man

14. Progress: A group of 30 experimental animals (*Macaca mulatta*) and 30 control animals were pair-matched by age, sex, weight, and medical history. The experimental animals were exposed continuously to magnetic and electric fields similar to those experienced by man in contact with the soil surface directly above a buried ELF antenna. Blood samples were drawn weekly for biochemical analysis. Physical examinations were given at six-week intervals by a veterinarian.

PUBLICATIONS:

Grissett, J.D., "Chronic Exposure of Primates to Electric and Magnetic Fields Associated with ELF Communications System", In: USNC/URSI 1976 Annual Meeting Abstracts, p. 145, Amherst MA, October 1976. Bioeffects Session to be published.

[ENCLOSURE 9]

NAVAL AEROSPACE MEDICAL RESEARCH LABORATORY, PENSACOLA, FLA., 32512, RESEARCH PROTOCOL FOR CHRONIC EXPOSURE OF PRIMATES TO ELECTRIC AND MAGNETIC FIELDS ASSOCIATED WITH ELF COMMUNICATIONS SYSTEMS. PRINCIPAL INVESTIGATORS: JAMES D. GRISSETT, PH. D., CHIEF, BIOMEDICAL DIVISION, NAMRL, JAMES L. KUPPER LCOL USAF VC, CHIEF, VETERINARY SCIENCES DIVISION, NAMRL

I. INTRODUCTION

Considerable research has been done at this and other laboratories to determine the physiological and psychophysiological effects of electric and magnetic fields with parameters similar to those that would be present near the antenna of the U.S. Navy's proposed ELF communications system. Exposure times have ranged from a few hours to seven weeks. Most parameters measured did not appear to be affected by the ELF fields; however, some parameters did show a statistical correlation with exposure, but for various reasons a firm cause and effect relationship could not be established. In many cases, the number of exposed subjects was small and/or the exposure times were short. Although not conclusive, these findings identified areas for further, more intensive investigation.

One series of experiments at this laboratory suggested that lipid metabolism might be affected by ELF magnetic fields. Ten human volunteers were exposed for periods of one day to a magnetic field of 0.1 mT (one gauss) at 45 Hz. Test results were compared for periods before, during and after exposure. At different times, five control subjects participated in the same experimental protocol except that the field generating coils were not energized.

No effects of the field were observed on ECG, vital signs, respiratory gas analysis, reaction time, pupillography, scotopic critical flicker frequency, short-term memory, and hand-eye coordination. Blood chemistry values were not changed with the exception of serum triglycerides which in nine experimental subjects reached a maximum 24 to 48 hours after exposure. A similar trend was not seen in the control subjects.

Another experimental series conducted at NAMRL was designed to detect changes in operant behavior of rhesus monkeys and squirrel monkeys exposed to ELF fields. These experiments covered a variety of behavioral tasks and exposure conditions but showed no behavioral effects that could be correlated with the fields.

In December, 1973 the Bureau of Medicine and Surgery, Department of the Navy, convened an "Ad Hoc Committee For the Review or Biomedical and Ecological Effects of ELF Radiation". Subsequently, the Biomedical Division, NAMRL developed a proposal which complied with and greatly exceed the intent of the priority 1a and 1b recommendation of this committee. The proposal was submitted to the Bureau of Medicine and Surgery on 2 April 1974. The project was approved and began 22 July 1974.

It was anticipated that approximately 2.5 years would be required to complete the project. Approximately one year would be required to construct and/or modify a building, design and fabricate apparatus, select experimental animals, assemble appropriate staff, and procure supplies and equipment. Exposure and data collection would occur during the second year. In the first half of the third year histopathological and histochemical examinations would follow and a project report prepared. This original estimate has been reasonably accurate. The building was completed 29 September 1975. During the month of October the fabricated apparatus, equipment, and supplies were moved into the building and assembled. The field was activated and exposure began in 27 October 1975.

The experimental protocol for the proposal is presented here and is intended to be comprehensive enough to allow professional research scientists to pass critical judgment on the overall design and specific methods. It does not include the detailed information necessary for a craftsman to construct each piece of apparatus and for a technician to assemble and adjust each measuring system. Such detail, including photographs, illustrations, engineering calculations and data, will be included in the final report.

The first section of this protocol is intended to provide a summary of the overall design. The remaining sections describe methods and procedures that fit together to implement the design. The pathology and histochemistry protocols are not included because the professional staff for this phase of the project will not be available before July 1976.

II. SUMMARY OF RESEARCH DESIGN AND METHODS

Essential design considerations for this chronic exposure are selection of animal species, number of animals, length of exposure, exposure parameters, and type of data collected.

The rhesus monkey (*Macaca mulatta*) was selected as the experimental animal because it is a highly developed species that has been used in medical research for many years; therefore, a large amount of physiological data has been accumulated on this species by the research communty. Adult rhesus were not included because of limited availability and logistical difficulties associated with care and handling of larger and stronger animals. Using adolescent animals of mixed sex presents some statistical difficulties but these problems are counterbalanced by gaining important data on growth and development.

In experiments of this type, in which subtle effects and trends within the normal range are vitally important, it is not sufficient for subjects to serve as their own controls by comparing pre-, per- and post-exposure data. In this project, each experimental animal will be pair-matched to a contol by age, sex, weight, and medical history. All data will be taken from both members of the pair at nearly the same time and under the same conditions.

The number of animals in each group was set at 30 because a sample of this size usually provides a sound basis for statistical analysis. Since each of the 30 experimental animals has a matched control, the groups are also matched. This arrangement allows for both group-to-group and animal-to-animal statistical calculations. An exposure time of one year was selected to allow time for subtle physiological effects to be detected and to provide a statistically large number of data points for each animal.

The animals in this experiment will be individually housed in a sealed chamber to allow for measurements of oxygen consumption and carbon dioxide production and to reduce the possibility of spreading a communicable disease among the entire group. Food, water, and excretion products will be carefully measured and a metabolic balance determined for each 7-day period. Blood samples will be drawn at intervals of seven days for biochemical analysis. Every sixth week the animals will be placed in restraint chairs for seven days. Blood samples taken during restraint will be analyzed for those constituents that are particularly labile and subject to the psycho-physiological stress normally associated with capture and manual restraint prior to venipuncture. At the end of each restraint period, the animals will be given a comprehensive physical examination by a veterinarian experienced in the clinical physiology of rhesus monkeys.

The experimental animals will be exposed to fields equivalent in waveform to those experienced by living organisms, including man, in contact with the soil surface directly above the buried ELF antenna. The magnitude of the magnetic field, 0.2 mT (2 gauss), will be 10 times greater than the worst-case condition at the ELF antenna. The electric field, 20V/m, is over 300 times greater than at the soil surface above and along the antenna; it is two times greater than at the soil surface near the ground terminal. The electric field will be applied to the animal via stainless steel bars which form the walking surface on the floor of the environmental chamber.

The facility is designed such that either the north or south wing can be used to expose experimental animals. Both wings have identical field generating equipment. When the experimental animals are in position in the north wing, the control animals will be in corresponding positions in the south wing but only the north wing field generating system will be energized. These identical systems will allow the two animal groups to be transposed each week, thus balancing any subtle differences in environmental control equipment, data transducers, recorders, noise level, vibrations, etc.

The ELF fields are on for 22 hours daily. The other two are used for feeding, drawing blood, physical examinations, changing cages and general maintenance activity. The lights in the animal wings are turned on at the beginning of this two hour period and remain on for twelve hours. The animals will usually consume their food within six hours after feeding. This factor in animal behavior and the twelve-hour dark period immediately before drawing blood insures a reasonably good fasting blood sample. At the end of the two hour maintenance period the field is restored, the animal rooms are locked.

At the end of the total exposure period (one year), half of the experimental and half of the control animals will be sacrificed and given an extensive pathological and histochemical examination. The remaining monkeys will be kept for at least two years and given a complete physical examination quarterly.

III. ANIMAL SELECTION, PAIRING, AND RANDOMIZATION

One-hundred and twenty rhesus monkeys were intially purchased in September 1974 and placed in quarantine for 6 weeks. During quarantine each animal was physically examined for evidence of infectious diseases and tested for tuberculosis. The entire group was released from quarantine after three consecutive negative intrapalpebral tuberculin tests. Blood samples were then obtained from each animal and a battery of biochemical and hematological tests performed. Means and standard deviations for each parameter were calculated for the entire group. Animals were excluded from further consideration of any of their lipid values or many of the other parameters were not within two standard deviations of the mean for the group. Complete physical examinations, as described under Clinical Examination, were then accomplished on the remaining monkeys. A total of 47 animals were deleted for various defects or abnormalities within the following categories: hematology—19, radiography—8, electrocardiography—9, dental—3, death or chronic illness—5, and miscellaneous—3. From the remaining 73 monkeys, 32 pairs were selected for the project on the basis of sex, age (dentition), weight and size. The 30 best pairs were identified for the project with the other two designated as alternates. Population data for the 60 selected monkeys has been developed as follows: mean age—47.2 months, age range—24 to 79 months, mean weight—4.98 kg, weight range—3.6 to 7.5 kg. The age distribution shows a clustering around 48 months which means most of the animals are pubescent or adolescent and are in a period of rapid growth. Projected weight gain per animal for the experimental period is in the range of 500 to 1000 grams. The animals are identified by tattoo numbers on the chest. One monkey of each pair was assigned to red group or blue group by the flip of a coin and the remaining member of the pair was assigned to the opposite group. Red and blue groups were designated experimental and control by the principal investigator without the knowledge of the other investigators. In this way a particular animal was grouped in a completely random fashion while the similarity between groups was maximized for increased statistical power.

IV. MAGNETIC FIELD GENERATING SYSTEM

The magnetic field generating system was designed to simulate the magnetic field associated with an ELF communication system. The current carrying conductors are beneath the animal chamber approximately the same distance as the buried cable of the communications system would be from the soil surface. The field direction is horizontal in the North-South direction and approximately one order of magnitude higher than in the ELF communications system.

The coil system consists of three parallel wire bundles 26 meters long. The bundles are spaced three meters and are connected at each end such that the entire system consists of a single continuous copper wire cable wound in the form of two adjacent rectangles with a long common side. The system generates a field of 0.2 mT (2 gauss) in the animal chamber placed 1.5 meters above the central wire bundle; simultaneously, the system will generate a null field in the control chamber placed along a parallel line 25.8 meters from the experimental chambers. The control chambers will be placed above a coil system that is identical to that which exposes the experimental animals. These identical coil systems allow the two animal groups to be periodically transposed. The two systems cannot be energized at the same time; the modulator and amplifier are switched to the other coil when the animals are transposed. The group first designated as experimentals retain that status; they are merely being exposed by a different coil system on the opposite side of the building.

At pseudorandom intervals the oscillator shifts between 72 Hz and 80 Hz. At the time of the shift the coil system is instantaneously tuned to the correct frequency. This automatic tuning is accomplished by solid state switching which changes the value of total capacitance that is in resonance with the coil system.

The magnetic field intensity at the floor level of the animal chamber is 0.23 mT (2.3 gauss). The approximate average value to which the animal is exposed would be 0.20 mT (2.0 gauss). This field is ten times greater than the maximum field near an ELF antenna.

V. ANIMAL CHAMBERS AND ELECTRIC FIELD GENERATING SYSTEM

Experimental and control animals will be housed in sealed chambers that use liquid rather than gasket seals. The bottom part of the four-piece unit consists of the feces tray with animal support bars. A narrow trough completely surrounds the feces tray. The middle part is open at the top and bottom and fits into the trough on the lower part. Another trough surrounds the top part of the middle section. The animal enters the chamber from the top and is secured by a sheet of plexiglass sliding in grooves at the top of the middle section. The animal's food and water supply is placed on this sheet and dispensed to the animal through appropriate channels. A final section similar to an inverted open box fits into the upper trough. An air tight seal is then created by filling the troughs with a suitable liquid. The liquid in the upper trough is water. Dimensions of the volume to which the animal is confined are 0.6 m × 0.6 m × 0.7 m high.

A nonconducting fluid is required in the lower trough because stainless steel strips pass through this liquid to provide an electrical connection between an outside current source and the stainless steel bars that form the walking surface for the animal. Each bar is connected to adjacent bars by resistors which stimulate the source impedance of soil near an ELF antenna element. The current applied to this network of resistors generates an electric field gradient of 0.75 volts between adjacent bars. The bars are constructed of 1.27 cm square stainless steel bar stock and spaced 3.81 cm between centerlines. An animal simultaneously contacting two or more bars will have a body current similar in waveform and magnitude to that which he would experience if he were in contact with the soil surface near the ground terminals of the ELF antenna. This simulated body current is 300 times greater than would be experienced along the antenna at points away from the ground terminal. The current source for this electric field simulator is driven by an amplifier with an input from the same modulator that drives the magnetic field generator.

The external environmental control equipment is connected to openings at the top and bottom sections of the animal chamber such that the flow of air is down through the center section, past the bars, into the feces tray, and out. The ventilation systems can operate either as an open system or as a closed recirculating system. In the open system mode, room air enters the chamber through a filter and air leaving the chamber is exhausted to the atmosphere.

The closed system mode is used to measure oxygen consumption and carbon dioxide production. In this arrangement air leaving the feces tray passes through 2 meters of plastic pipe to another, but much smaller, sealed chamber. The air is driven by a tube-axial fan in this chamber which forces the air through carbon dioxide absorbant, a heat exchanger, and back to the top of the animal chamber. The heat exchanger has a constant flow of 25°C water and removes body heat and heat generated by the reactions associated with carbon dioxide absorption. Pressure is maintained in the system by allowing pure oxygen to enter at the same rate as that it is removed by the metabolic process.

Oxygen entering the system passes first through four stages of regulation and a wet test gas meter. The combined function of the regulators is to keep the static pressure on the chamber between 2 and 4 cm of water which will not break the liquid seals on the chamber. The wet test meter measures oxygen consumption rate by triggering an event recorder at 500 ml intervals. The total oxygen consumed is also indicated by the totalizing dials on the gas meter. The carbon dioxide expiration rate is measured for a 22 hour period by chemical analysis of the absorber to determine the total amount of carbon dioxide absorbed.

The system is operated in the closed circuit mode for a 22 hour period at seven day intervals. It is always the first 22 hours after the animal has been placed in a clean chamber thus preventing the animal from rebreathing gases evolved from accumulated feces and urine. The remaining six days are in the open circuit mode with ventilation to the atmosphere.

VI. CLINICAL EXAMINATION AND ROUTINE MONITORING

Members of a matched pair are given physical examinations at the same time. The examining veterinarian and his staff do not know which animal is an experimental or a control. Part of the examination precedes a seven day period in which the animal pair is confined to restrain chairs; the remaining part of the physical follows this restraint period. Electrocardiograms, electroencephalograms, and systolic blood pressure (Doppler method) are completed prior to the restraint period. After the restraint period the pair is given a comprehensive examination which includes the following: observation of ocular motility, direct and indirect pupillary reflexes, facial muscle tone, locomotor and proprioceptor activity, disposition and demeanor; visual and manual examination of head, face, scalp, neck, mouth, teeth, throat, extremities, skin, haircoat, superficial spine, and perineal region; direct ophthamolscopy; otoscopic visualization of external auditory canal and nares; palpation of abdomen, superficial lymph nodes, femoral pulse, and inguinal canals; auscultation of heart and lungs; elicitation and evaluation of the palmar, plantar, patellar tendon, superficial abdominal and auditory-palpebral reflexes. Rectal swabs are taken for bacteriologic examination. These comprehensive examinations are given at six-week intervals.

In addition to the physical examinations, the veterinarian and his professional staff perform the following tasks daily: surveillance of blood collection and temperature probe attachment; daily rounds—visual examination of every monkey and chamber, including treatments, followup observations and notes on estrous cycle phases; quality assurance and daily intake of food and water on all animals; check of weight charts of animals weighed on that day; sanitation inspection of animal areas, examination room, cage, chamber and chair washing and storage areas; collection of bacteriological samples on a regular schedule from all animal associated areas.

VII. BLOOD CHEMISTRY

Blood samples are drawn by venipuncture from the femoral vein early in the morning with the animals in a fasting condition. The laboratory technical drawing the blood writes the animal's identification number on the sample tube at the time it is drawn. Before the samples are delivered to the laboratory, the animal's identification number is removed and replaced by a control number. A permanent bound record which matches the animal number and control is kept in a secure safe and is not available to the medical technologists who are analyzing blood samples. This prevents the medical technologists from knowing which data belongs to an experimental or a control.

The blood samples are analyzed for the following parameters using the indicated methods. Control serum of known value is analyzed in the same batch with the animal serum to insure quality control.

Parameters	*Method*
1. Total protein	Biuret.
2. Albumin	Bromcresol green.
3. SGOT	Kinetic-malate dehydrogenase.
4. SGPT	Kinetic-lactate dehydrogenase.
5. LDH	NADH production.
6. CPK	G–6–PDH production of NADH.
7. BUN	Urease and glutamate dehydrogenase production of NAD+.
8. Glucose	Hexokinase and G–6–PDH production of NADH.
9. Cholesterol	Peroxidase-quinoneimine dye.
10. Triglyceride	Enzymatic measuremnet of glycerol by decrease in concentration of NADH.
11. GGTP (gammaglutamyl transpeptidase).	Enzymatic production of p-nitroaniline.
12. PHI (Phosphohexose)	Glucose phosphate isomerase and G–6–PDH production of NADH.
13. Calcium	Calcein fluorometric titration using corning calcium analyzer.
14. Chloride	Coulometric titration using corning chloride meter.
15. Sodium	Flame photometer.
16. Potassium	Flame photometer.
17. Serum protein	Cellulose acetate film.
18. Lipoprotein	Agarose gel film.
19. T_3 (Total hormonal triiodothyronine).	Radio immunoassay.
20. T_4 (Total hormonal thyroxine)	Radio immunoassay.
21. C.B.C. (Includes white blood count, red blood count, hematocrit, hemoglobin, MCV=mean corpusular vlune, MCH=mean corpulsar hemoglobin, MCHC=mean corpusular hemoglobin concentration differential).	Coulter counter model ZBI with model 1000 channelyzer and hemoglobinometer.

The above tests are done routinely on fresh serum samples. Part of each sample is preserved at −85°C to be used for other tests that may be desired at a later time.

Results of all tests are recorded on a permanent bound log which is retained in the analytical laboratory. This log is copied and entered into an electronic file system where it is electronically matched to the animal identifying numbers and electronically filed according to animal number and group designation. The data is then available for analysis.

VIII. START-UP PROCEDURE AND SCHEDULE

The start-up procedure and schedule was designed to allow data on each animal to be taken at the same intervals of exposure. For example, the total exposure time for any animal at his third physical examination is identical to the exposure time for all other animals at the third physical examination. The same is true for all data, i.e., the 33rd blood sample is drawn after the same days of exposure for all animals. To assemble a staff sufficient to give sixty physicals, draw sixty blood samples and in general collect the same data on all animals on the same day would have increased the cost of the project approxiamtely five fold. The following schedule was therefore prepared to minimize cost by distributing the workload over a six week period without losing scientific rigor or compromising the statistical validity of the data.

On Monday, 27 October 1975, pair number one was brought from the vivarium in Building 1953 to the ELF Building. An EEG and ECG were recorded for each animal. One animal was then placed at position one over the north simulator and the other animal in the corresponding position one over the south simulator. The staff members placing these animals had no knowledge of which simulator would be energized. The decision to energize a specific simulator was then made by the principal investigator who at that point had no knowledge of which animal had gone to the north or the south side.

Pair one was henceforth designated a Monday pair which means that every Monday morning blood samples are drawn, cages are changed and configured for a close system to monitor oxygen consumption rate. On Tuesday, 28 October, pair number two was introduced into the experiment and would henceforth be designated as a Tuesday pair. The procedure continues with one additional pair of animals entering the experiment each weekday for six weeks. During the first seven days, each pair was confined to a restraint chair and blood samples were taken daily to record possible transient effects.

The clinical state of each animal was well established prior to entering the experiment. The first clinical observation after beginning the experiment occurs on day seven at the end of the initial restraint period. This early physical after only seven days of exposure was intended to provide clinical documentation of transient effects. The remaining physicals are at six-week intervals and always follow a seven day restraint period.

On Monday, 1 November 1976, pair number one will have completed 371 days in the experiment and will be removed from the ELF facility and returned to the vivarium. One pair will be removed each succeeding weekday until pair number thirty is removed on 10 December 1976. Prior to this final six weeks, half of the male and half of the female pairs will be designated for pathological examination. Upon removal to the vivarium a designated pair will be prepared immediately for examination. The remaining pairs will be retained in the vivarium for continued observation.

[ENCLOSURE 10]

BIOLOGIC EFFECTS OF ELECTRIC AND MAGNETIC FIELDS ASSOCIATED WITH PROPOSED PROJECT SEAFARER

COMMITTEE ON BIOSPHERE EFFECTS OF EXTREMELY LOW-FREQUENCY RADIATION

ASSEMBLY OF LIFE SCIENCES

Mitoses in a large multinucleate cell. The absence of blind scoring was of special concern, because subconscious investigator bias is widely recognized as a source of error in science (as discussed earlier). From the data available and with the proposed ELF fields and frequencies, the Committee does not believe that the effect, if confirmed, is reason for concern. Other aspects of the growth and physiology of the cells appeared normal. The Committee nevertheless believes that there should be continued study of this general question, possibly with different types of experimental material.

Serum Triglycerides

Serum triglyceride concentrations in connection with ELF fields have aroused much interest and concern. The question originated with a study at the Naval Aerospace Medical Research Laboratory at Pensacola in 1971, which indicated that serum triglyceride content might be increased as a consequence of exposure to an ELF field. The researchers themselves questioned the validity of the observations; of a large battery of determinations, this determination was the only one in which some possible effect was suggested, and its relation to the ELF field was not clear. The experiment was discussed by an ad hoc Committee for the Review of Biomedical and Ecological Effect of ELF Radiation in a meeting (December 6–7, 1973) sponsored by the U.S. Navy Bureau of Medicine and Surgery. The ad hoc committee pointed out that the number of subjects was too small to exclude other possible causes and that the experimental design was inadequate in other respects. A study of personnel at the Wisconsin Test Facility was also deficient in many respects.

The ad hoc committee recommended (1973) the development of experiments with an appropriate animal model and studies with humans. Research has now been carried out with monkeys over extended periods, under nearly ideal conditions, and with excellent protocols. It yielded no indication of any changes in a variety of measured physiologic characteristics, including serum triglyceride content. The present Committee has not adopted the recommendation of studies with humans. Properly designed human studies present many difficulties; and human experiments with triglycerides compound the difficulties, because the values in man are known to be capricious and subject to a variety of poorly understood factors, such as stress in confinement and dietary replication. There is reason for much (perhaps more) confidence in well-described and well-executed experiments with animal models. On the basis of these experiments, the Committee believes that Seafarer fields will not have an effect on human triglyceride concentrations.

Circadian Rhythmicity

Circadian rhythmicity is related to the daily physiologic cycles exhibited by man and other organisms—for example, the sleep-wakefulness cycle and daily temperature cycles.

Circadian rhythms have been reported by some workers to be sensitive to ELF fields. Effects in human subjects have been reported by one laboratory. The experiments involved shielding against the natural background fields; there was a very slight increase in the period of the daily rhythm (about 15 min out of 24 h) and desynchronization between different rhythmic functions. These changes could be reversed (to normal) by the introduction of a weak electric field at 10 Hz. The proposed Seafarer antenna would be different: it would *add* to the natural background, not eliminate it, and the Seafarer frequency would be about 76 Hz, rather than 10 Hz.

Triglycerides

The appearance of two reports in 1973 caused some concern about whether the electric or magnetic fields associated with Seafarer cause increases in human triglyceride concentration.[1] [2] One paper reported on men and women at the Wisconsin Test Facility, and another on men at an experimental facility at the Naval Aerospace Medical Laboratory in Florida.

BACKGROUND

Triglycerides constitute one of the three major lipid groups found in the plasma. Dietary fat is predominantly triglycerides. Approvimately 1–2 g of triglyceride per kilogram of body weight is consumed daily by the average person. These triglycerides undergo partial hydrolysis in the intestinal lumen and are taken up with other lipids into the numosal cells, where they are reformed and assembled into particles called chylomicrons. The chylomicrons enter the systemic circulation via the lymphatic system and are removed from the blood by the action of lipoprotein lipases. Chylomicron triglycerides are described as exogenous in origin.

Triglyceride may also be of endogenous origin, in the form of very-low-density lipoproteins (VLDL). These are synthesized mainly in the liver from such precursors as free fatty acids and excess carbohydrate. VLDL are also removed

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from the circulation through lipoprotein lipase activity. This process is associated with the formation of low-density liproproteins (LDL).

Plasma triglyceride concentrations reflect the concentrations of chylomicrons and VLDL in the plasma. Normal fasting plasma does not contain chylomicrons, and disorders resulting in fasting chylomicronemia are rare and easily recognized. Hypertriglyceridemia due to VLDL increase, the most common cause of hypertriglyceridemia, is called type IV hyperlipoproteinemia. A rarer form of hypertriglyceridemia, type III, results from abnormal VLDL. Type V hyperlipoproteinemia involves a combination of chylomicronemia and increased VLDL and is rarer than type IV. In type IIb hyperliproproteinemia, LDL, VLDL, cholesterol, and triglycerides are all increased; it is not frequent.

Sampling for Hypertriglyceridemia. Because of the influence of fat ingestion, it is necessary to standardize sampling for triglyceride evaluation. It is customary to sample after a 12- 16-h fast, by which time a normal postprandial chylomicronemia will have disappeared. Many factors influence triglyceride concentrations, such as pregnancy and medications. The status of the subject with respect to these should be taken into account in evaluating triglyceride concentrations.

Signifiance of Hypertriglyceridemia. Hypertriglyceridemia due to severe chylemicronemia is associated with distinct clinic phenomena that are uncommon and sometimes dangerous, but easily recognized. The more common types of hypertriglyceridemia, such as type IV hyperlipoproteinemia, are not unequivocally proved to be associated with coronary heart disease. In contrast with increased cholesterol, for which prospective studies have demonstrated an increased risk of coronary heart disease, corresponding studies of triglyceride have yielded contradictory and inconclusive results, so increased triglyceride content is not currently an established risk factor for coronary heart disease. Hypertriglyceridemia is thought to be undesirable in general terms, often reflecting such factors as dietary excess and alcohol consumption.

Normal Limits for Triglyceride. Conventionally, the 95th percentile for triglyceride is usually selected to define abnormality. Age-specific National Heart, Lung, and Blood Institute (NHLBI) cutpoints ranging from 150 to 190 mg/100 ml are now used. However, data about to be published from the Lipid Research Clinics Program, NHLBI, indicate that the 95th percentile varies from 250 to over 300 mg/100 ml in men and from 200 to 250 mg/100 ml in women. Application of the currently used NHLBI cutpoints thus tends to overdiagnose type IV hyperlipoproteinemia.

Problems in Evaluating Hypertriglyceridemia. Triglyceride concentrations are much less stable than cholesterol concentrations. They are subject to a variety of common influences such as diet, caloric intake, alcohol intake, stressors, medication, and menstrual status. Considerable fluctuations may occur in evaluating a subject from day to day. It is generally recommended that at least two baseline measures be made in evaluating a person's triglyceride status.

This instability is also reflected in the difficulty in conducting studies of the impact of agents on triglyceride content. Ideally, such studies should be carried out in a metabolic ward with strict dietary control, so that the variable under evaluation can be assumed to be the factor responsible for any observed differences. In practice, for these reasons, triglycerides have been studied much less frequently than cholesterol, e.g., in examining drug effects.

Mechanisms of Hypertriglyceridemia. Although hypertriglyceridemia is common and has been subject to a great deal of investigation, there is no consensus regarding the mechanisms of hypertriglyceridemia in the majority of subjects. There is evidence of increased production, decreased utilization, and both. The problems in this field are related to methodologic difficulties and the difficulty in obtaining a steady state.

STUDIES

Three experiments were undertaken by Beischer *et al.*[2] In the first, two subjects were confined to a chamber together for 3 days. A 1–G (45-Hz) field was applied during day 2 for about 10 h. Preexposure triglyceride values were obtained 9 days before confinement; both subjects' triglyceride values were higher after the exposure. One subject was a type IV hyperlipidemic. There was no dietary control. There were no control (sham) subjects.

In the second experiment, two persons were confined and exposed; an additional subject served as a sham control. One experimental subject and the sham control were hyperlipidemic; the second experimental subject was apparently

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normal. Diet was restricted to a choice of meals prepared by a Navy hospital. Confinement was for 7 days, with a 22.5 h 1-G (45-Hz) exposure halfway through. Preconfinement triglyceride values were minimal in number (one or two). One exposed subject showed a large "spike" in triglyceride values 24 h after exposure amid otherwise normal values.

The third experiment (7 days long with a 1-G exposure for 22.5 h halfway through) involved several sets of participants. In the first exposure set, two subjects' triglyceride values were ascending before the field was turned on and continued to rise until 48 h after field application, placing them above the "normal" range. The next pair of exposed subjects had increased triglyceride 48 h after exposure (with one above "normal") ; both subjects had relatively stable values before field exposure. However, the two subjects had an argument during the fourth evening, and their increases could be attributed to the stress of the argument and confinement. Two subjects served both as control and as experimental subjects, and their values show no consistent pattern with respect to whether the filed was on; there was considerable and comparable variability in their triglyceride values. None of the control subjects had any "abnormal" values, but there was considerable variability.

Beischer's experiments suffered from several design deficiencies: the diet was not controlled, the subjects were not matched, there was an absence of critical preexposure (fasting) baseline data for all subjects, there was an absence of specific information on dietary compliance, and, except for two subjects, there was no determination of the effect of confinement itself. The exposed men consisted solely of various categories of aviation officer "dropouts"; Navy corpsmen served only in the control group. Beischer stated that "no effects were seen that could definitely be linked with the magnetic field; however, serum triglycerides in most subjects appeared to be affected by some factor or combination of factors associated with the experimental protocol. . . . The number of subjects is too small however, to exclude statistically other factors such as psychophysiological reactions to forced changes in personal living habits, modified activities, restricted diet and confinement." We believe that this report does not support an effect of a magnetic field on human triglyceride concentrations.

In another study, Beischer and Brehl[3] used 140 8-week-old virgin female white mice; 70 mice were exposed for 24 h to a 1-G 45-Hz field, and the other 70 served as sham controls. After exposure, each day for 7 days, 10 mice from each group were sacrificed, their livers were removed, and the amount of triglyceride (as indicated by glycerol) was determined. There was no statistically significant difference in triglyceride content between the two groups.

All these experiments[2, 3] used determinations of endogenously produced triglycerides. In the human experiments, fasting blood values represented what was produced endogenously and was circulating in the blood. In the mouse experiment, the liver triglycerides represented endogenous production. The mouse experiment was the better controlled, and thus more reliable, experiment. None of them supported a causal relationship.

Grissett and Kupper[4] exposed rhesus monkeys to ELF electric and magnetic fields for more than a year in an extremely well-controlled experiment. In exposures lasting 22 h/day, field strengths of 2 G and 20 V/m were used at a frequency that shifted at pseudorandom intervals between 72 and 80 Hz. There were 28 animals in each of the exposed and control groups paired on the basis of sex, weight, approximate age, triglyceride content, and other factors. Which group was which was not known to those involved in the immediate conduct of the study. Triglyceride contents were determined weekly. There was no significant difference between the exposed and control groups.

Rupilius[5] found no differences in triglyceride values up to 24 h after exposure between control and experimental humans exposed for 3 h to a 50-Hz, 3-G magnetic field in combination with a 20,000-V/m electric field.

Mathewson[6] exposed 180-q male rats (48 experimental and 48 control) to a 20-V/m, 45-Hz electric field for 28 days. No statistical difference in triglyceride values was observed between the two groups.

The Wisconsin Test Facility (WTF) studies, which also gave rise to concern about possible Seafarer effects on triglyceride content, began in 1970. The "exposed" group consisted of 24 people at the facility. A control (unexposed) group was established at the Midwest Naval Electronic Systems Command at Great Lakes, Illinois. The control group also consisted of 24 people, each matched

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for sex and age with a member of the exposed group. All 48 people were examined during the period from late 1970 to early 1971. Examinations were repeated a year later. However, only 12 test subjects and 21 control subjects reported for the followup examination. Only nine of the matched pairs were left intact.

One report indicated that the exposed group had increased triglyceride values.[1] (This statement was later discussed in Congress and in the press.) However, another report indicated that increased triglyceride was found in both the exposed and the control groups.[7] In the most recent report on this research, Houk[8] concluded that continued medical surveillance had not provided any evidence that exposure to the ELF electric and magnetic fields of the antenna bore any causal relationship to increased serum triglyceride.

The Committee believes that, although the WIF studies provided no evidence of an effect of ELF fields on triglyceride content, these studies would be able to demonstrate only an overwhelming effect, because of the following deficiencies:

The sample was too small to provide significant results after many members of the original groups dropped out.

As the investigators noted, one laboratory method of determining triglyceride content was used in the first examination, and a second method was used a year later.

Of the 18 people in the final matched pairs, five had diabetes, 10 were overweight, and six had an "alcohol excess" problem. These conditions were nearly evenly divided between groups. They further confounded the results, because all three conditions can affect triglyceride content and its variability.

Proper steps were not taken to ensure that subjects actually did not eat during "fasting" periods before examination. Comparison of triglyceride contents is meaningless if the fasting status is uncertain.

CONCLUSION

We believe that the studies that reported triglyceride increases associated with ELF fields had serious control deficiencies and that the well-controlled studies did not show any such association. Therefore, we believe that Seafarer fields will not have an effect on human triglyceride concentration. We believe that there is abundant evidence, as cited here, to support this conclusion, so that additional research in the field is not necessary.

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Rats: A search for Growth, Food Consumption and Blood Metabolite Alterations. Bethesda, Md.: Armed Forces Radiobiology Research Institute, Defense Nuclear Agency, 10 January 1977, 61 pp.

7a. Krumpe, P. E., and M. S. Tockman. Evaluation of the Health of Personnel Working Near Project Sanguine Beta Test Facility from 1971 to 1972.

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7b. Krumpe, P. E., and M. S. Tockman Evaluation of the health of personnel working near Project Sanguine Beta Test Facility from 1971 to 1972, pp. 98–122. In J. G. Llaurado, A. Sances, Jr., and J. H. Battocletti, eds. Biological and Clinical Effects of Low Frequency Magnetic and Electric Fields. Springfield, Ill.: Charles C. Thomas, 1974.

8. Houk, W. M. The Continuing Medical Surveillance of Personnel Exposed to Extremely Low Frequency (ELF) Electromagnetic Fields. Report No. NAMRL–1225. Pensacola, Fla.: Naval Aerospace Medical Research Laboratory, 1976. 17 pp.

[ENCLOSURE 11]

DEPARTMENT OF THE NAVY,
NAVY ENVIRONMENTAL HEALTH CENTER,
Cincinnati, Ohio.

From: Commanding Officer, Navy Environmental Health Center.
To: Chief, Bureau of Medicine and Surgery, Washington, D.C. 20372.
Subject: Industrial/Radiological Health Evaluation of TACAN Repair Facility Workplace; report of.
References: (a) CHBUMED ltr BUMED–55–DFH:jp 6470 22 Nov 1976. (b) BUMEDINST 6470.13A. (c) NAVMED p–5055.
Enclosures: (1) List of Survey Team Members. (2) Summary Report of Radiation Surveys.

1. In accordance with reference (a), subject surveys were performed at Naval Air Rework Facilities in Norfolk, VA, Jacksonville, FL, and Pensacola, FL. Enclosure (1) lists the members of the survey team for these evaluations.

2. Enclosure (2) summarizes the results of the radiation hazards surveys at these facilities. There were no levels of microwave radiation, in excess of the limits set forth in reference (b), found during any of the surveys. No ionizing radiation in excess of the limits of reference (c) were noted during the surveys.

3. Medical personnel reviewed the health records of all known TACAN repairmen currently employed at these facilities. They were unable to notice any pattern of abnormalities in these workers. At this time it is difficult to determine the feasibility of further epidemiological studies due to inability to identify previous workers.

4. An industrial hygiene survey of the chemical substances used revealed nothing of significance. Cleaning solvents and lubricants are used in such small quantities that personnel exposures are of little concern. The composition of several commercial products is still being investigated. Should a substance of concern come to light, this data will be forwarded. Concern was expressed about the possible use of carbon tetrachloride. As near as could be determined the last usage of carbon tetrachloride occurred in 1958.

5. Based upon the findings of these surveys the following observations have been made:

(*a*) The radiation levels, both ionizing and non-ionizing, are well within established limits for safe personnel exposure.

(*b*) The work habits of repair personnel, and the small quantities of chemicals they use, are not considered hazardous to their health.

(*c*) The likelihood of a meaningful epidemiological study of TACAN workers is doubtful due to lack of information.

(*d*) The need for further industrial/radiological surveys is considered to be necessary.

6. Please contact the Navy Environmental Health Center (NAVENVIRHLTH CEN) (LT M. G. Knight) if additional assistance or clarification is desired. Autovon 989–3863, Commercial 513/684–3863.

R. L. WILLIAMSON,
By direction.

LIST OF SURVEY TEAM MEMBERS

Name	Organization	Title
Capt. D. F. Hoeffler, MC, USN (Norfolk only)	BUMED Code 55	Director, Occupational and Preventive Medicine Division.
Lt. Comdr. L. G. Beuchler, MSC, USN (Jacksonville/Pensacola only).	BUMED Code 5321	Head, Non-Ionizing Radiation Section.
Lt. Comdr. R. L. Johnson, MSC, USN	NAVENVIRHLTHCEN	Head, Field Services Branch.
Lt. M. G. Knight, MSC, USN	NAVENVIRHLTHCEN	Head, Radiation Health Branch.
Lt. G. E. Williams, MSC, USNR (Jacksonville/Pensacola only).	NAVENVIRHLTHCEN	Radiation Health Officer.
J. K. Wagoner CO-06 (Norfolk/Jacksonville only)	NIOSH	Chief, Industry Wide Studies Branch.
J. S. Taylor, GS-14 (Jacksonville/Pensacola only)	U.S. Army Environmental Hygiene Agency.	Acting Chief, Laser/Microwave Division.
W. L. Smith, GS-14	NAVENVIRHLTHCEN	Chief, Occupational Medicine Division.
W. Parr, GS-14	NIOSH	Chief, Physical Agents Effects Branch.
E. Eagen, GS-9 (Norfolk/Jacksonville only)	NIOSH	Epidemiologist.
G. K. Smith, GS-12 (Norfolk only)	Naval Regional Medical Center, Newport, R.I.	Safety Manager.

SUMMARY REPORT OF RADIATION SURVEYS FOR NAVAL AIR REWORK FACILITIES NORFOLK, VA., JACKSONVILLE, FLA., AND PENSACOLA, FLA.

Conducted by: M. G. Knight, LT MSC USN, Radiation Health Officer; W. H. Parr, Ph.D., Chief, Physical Agents Effects Branch, National Institute for Occupational Safety and Health.

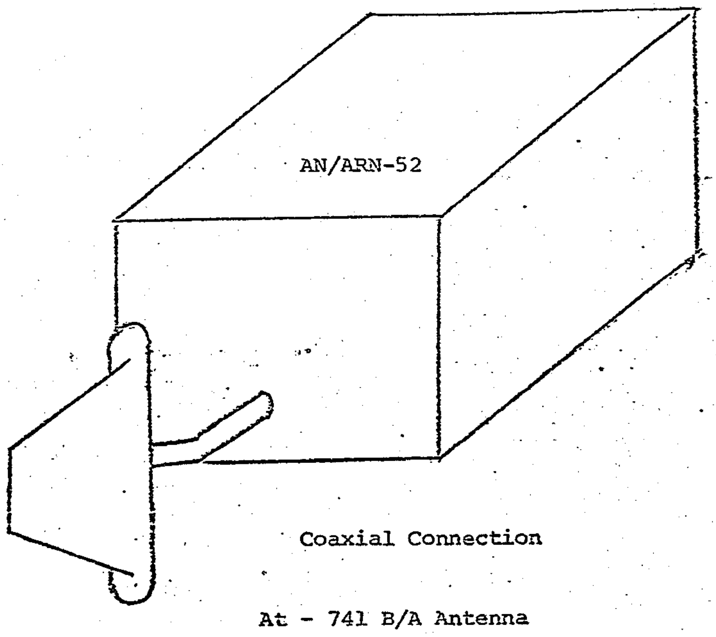
Released by: T. N. Markham, Captain MC USN, Commanding Officer.

The signal transmitted by airborne TACAN equipment consists of pulse pairs broadcasted in the frequency range 1025 megahertz (MHz) to 1150 MHz. Depending on the mode of operation these pairs are spaced 12 microseconds (μsec), 24 μsec, or 36 μsec apart (with each pulse having a duration of 3–4 μsec), and are repeated at the rate of 150 pairs per second for air to ground and not less than 22 pairs per second for air to air. The power output and operating voltages may vary depending on the type of unit. These are normally in the range of 1 to 4 kilowatts and 2 to 4 kilovolts respectively. Survey equipment used to evaluate health hazards at the three facilities consisted of Narda Models 8310 and 8315, radiation monitors with model 8323 and 8321 probes, capable of responding to frequencies of 300 MHz to 18GHz. Additionally, a Victoreen 440 RF/C survey meter was used to detect the presence of x-ray.

At the facility in Norfolk, VA, surveys were performed on the AN/ARN–21, AN/ARN–52, AN/ARN–84 TACAN units and the AN/ARM–22 test simulator. The only detectable microwave radiation for the AN/ARN–21 was 1.5 mW/cm^2 found when the shields and covers were removed from the power tubes. There was no detectable x-ray production from this unit. The AN/ARN–52 showed no detectable microwave radiation, even with the caps and shields removed from the power tubes. The I.F/Modulator section of this unit did show 0.2 mr/hr x-ray directly on the surface of the unit, this fell off to zero at one centimeter. The only detectable microwave radiation from the AN/ARN–84 was found when the power cavity was fully exposed. In this condition a level of 0.1 mW/cm^2 was found when the probe was placed in contact with the surface of the cavity. There was no detectable x-ray production. The AN/ARM–22 simulator was surveyed in both the operational and maintenance configurations. The only detectable microwave radiation was 1.2 mW/cm^2 directly on the frequency preselector when exposed for maintenance. There was no detectable x-ray production.

Figures 1 and 2 show configuration and measurements of AN/ARN–52 as set up at the Jacksonville facility for air to air transmission. In addition to these tests some AN/ARN–52 units were checked in a regular maintenance configuration. With all shields and covers removed from the power section a maximum reading 0.05 mW/cm^2 was found on the surface. This reading was consistent at a pulse repetition rate of both 27 and 150 pairs per second. There was no detectable x-ray production. The AN/ARN–21 showed no microwave or x-ray radiation even when the unit was completely devoid of shields. The AN/ARN–22 showed no detectable microwave or x-ray radiation.

Table I gives the results of survey performed at Pensacola. Due to equipment malfunction on x-ray survey was not performed at this facility.

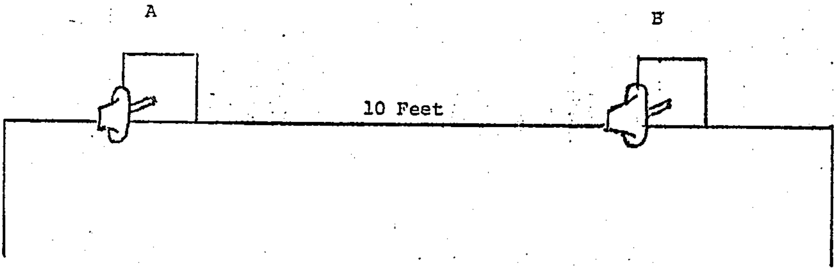

AN/ARN-52
Coaxial Connection
At - 741 B/A Antenna

Location on Antenna	Power Density (mW/cm^2)
Top Edge	0.3
Bottom Edge	0.3
Leading Edge	0.2
Behind	2.5
Side Surface	1.2
12 inches from side	0.4
24 inches from side	0.07
36 inches from side	0.05
40 inches from side	No detectable readings

Setup of AN/ARN-52 for live transmission

FIGURE 1

CONFIGURATION OF AN/ARN-52s FOR AIR TO AIR
TRANSMISSION ON THE WORKBENCH
NAVAIREWORKFAC JAX



TRANSMITTER A		TRANSMITTER B
Power 2.0 KW		2.5 KW
0.8 mW/cm^2	On Antenna Surface	1.4 mW/cm^2
0.3-0.7 mW/cm^2	3 inches from antenna	1.0 mW/cm^2
1.7 mW/cm^2	Between Antenna and transmitter	2.8 mW/cm^2

Halfway between the antennas: 0.04 mW/cm^2

FIGURE 2

TABLE I.—RADIATION SURVEY RESULTS[1] AVIONICS FACILITY, NAVAL AIR REWORK FACILITY, PENSACOLA, APR. 27, 1977

Instrument	Situation/Location						
	ARN 52 air-air at cavity	ARN 52 search at caps	ARN 52 at cap, shield removed	ARN 105 at cap	ARN 21 air-air at power tubes	ARN 21 No. 2939 search at antenna	ARN 21 search at antenna
NARDA 8310 with 8323 probe	NDR	NDR	0.02	NDR	0.03	2	1.0
NARDA 8315 with 8321 probe	NDR	NDR	.02	NDR	.07	3	1.7

[1] Readings are in mW/CM^2.

Note.—NDR indicates no detectable reading.

[Enclosure 12]

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
April 21, 1977.

To: Director, DBBS.
From: Chief, PAEB.
Subject: Trip Report to Norfolk, Va., Travel Order No. 057054. Left Cincinnati, Ohio on April 11, 1977 at 8:15 a.m.

The survey team (attachment #1) met with Norfolk Naval Base personnel, both individually and as a group, to discuss the purpose and objectives of the TACAN survey. The Commanding Officer, Captain Williams, expressed his appreciation with NIOSH's participation. He cited an incident during his last command where NIOSH was invited in and resolved a noise problem with the union. A special effort was made by Capt. Williams for us to meet with union representatives before invading the shop areas. All supervisors and foremen were advised to give us complete cooperation.

Measurements were made on three different TACAN models, AN/ARN–21, 52 and 84.

The ARN 21 and 52 units received special attention as these models were the ones generally repaired by Mr. Donald Cadieux (deceased) and Mr. Robert Engells. (Mr. Cadieux's family and Mr. Engells', who is now confined to bed, each have 4.2 million dollar lawsuits against the manufacturers of the TACAN units.)

The equipment used in making microwave radiation measurements consisted of:

1. Hewlett-Packard Power Meter with standard gain horns
2. EDM–3 especially developed for the Navy by NBS
3. Narda Model 8310
4. Narda Model 8315
5. Victoreen 440 RFC for measuring ionizing radiation.

Before making measurements the specifications for each of the TACAN models were reviewed. To our surprise none of the models utilized a klystron tube but had 4 power tubes in the modulator cavity with a maximum power of 2 to 3.2 kilovolts. This is considerably below the 20 KV required to produce tube penetrating x-rays. Measurements, however, were made in all cases to detect x-rays.

Gordon Smith, the Safety Officer at Naval Regional Medical Center, Newport, Rhode Island, reviewed the work practices employed by the TACAN Maintenance personnel and Lt. Comdr. Johnson, Naval Industrial Hygienist searched the shelves for toxic solvents.

Dr. Smith (USN), Dr. Wagner (NIOSH) and Mr. Eagan (NIOSH) were to meet and review health records on Wednesday, April 14, 1977.

All units were monitored as listed for the AN/ARN 21, however, only the pertinent results are reported for the other TACAN models. The maximum radiation levels measured were as follows:

AN/ARN–21

Frequency: 962–1213 MHz.
Power Output: 1–2 KV.
126 channels.

Radiation detected from:

1. End of unit	0
2. Bottom of unit	0
3. From top of unit	0
EDM–flush on power tube	4.2 mW/cm²
Narda 8310 flush on modulator	0
Narda 8315 flush on modulator	0
Hewlett Packard flush on modulator	0
4. Caps removed from power tubes No. (JAN) 7289, EDM–3	
Microwave	4.8 mW/cm²
Narda 8315	1.5 mW/cm²
5. Other meters	0
6. X-rays	0

AN/ARN 52

Frequency: 962–1150 MHz.
Power output: 1.2–3 KV.
126 channels.

1. Microwave radiation	–0
X-rays (I.F.)	0.2 mR
Plate removed from cavity	–0
X-rays (I.F.)	–0.2 mR

AN/ARN 22 Radio test set TACAN simulator.

Microwaves, EDM–3 (flush on frequency preselector)	15 mW/cm²
Narda 8310 (flush on frequency preselector)	1.2 mW/cm²
X-rays	0

AN/ARN 84 (new transistorized unit).

All meter readings 0 with unit in tact.

At our request a unit was disassembled to allow measurements through a maintenance repair procedure. Cavity (power tubes) measurements were the following:

EDM-3	0.5 mW/cm^2
Narda 8310	0.1 mW/cm^2
Narda 8315	0.1 mW/cm^2
Victoreen 440 RF	0 (x-rays)

The difference in the meter readings were of concern until investigation revealed that each probe had a spacer of different thicknesses protecting the sensitive detective element. Similar readings were obtained at equivalent distances.

Upon completion of the survey a debriefing procedures was followed. In addition to the names listed in the attachment we met with Captain W. Brownlow, M.D., Commanding Officer, Preventive Medicine Unit No. 2 (East Coast, United States and the Atlantic Fleet) and the Industrial Hygienist, Lt. Craig Morin, another meeting with Commanding Officer Capt. Sam Powers, M.D., Norfolk Naval Shipyard Dispensary and Capt. Sam Barboo, Chief Industrial Hygienist, Norfolk Naval Base, and Mr. Larry Hacker, Chief Salary Officer, Norfolk Naval Shipyard.

Apparently the alleged pancreatic cancer problem associated with TACAN repairmen has become widely known throughout the NARF repair shops. The Naval BuMed and the Naval Environmental Health Center here in Cincinnati have received telephone inquiries from Alameda, San Diego, Jacksonville, Pensacola and Cherry Point, N.C. requesting hazard evaluations of the TACAN repair unit. Apparently some of the maintenance personnel are questioning their safety in working with this instrumentation. Present plans as agreed to at the last NIOSH-Navy meeting are to evaluate one other NARF operation, probably Jacksonville, Florida.

According to Gordon Smith the only condition that existed in the Quonset Point shop that we were unable to duplicate was measurements during air to air transmission. Lt. Knight (USN) is calling for assurance that the air to air measurements can be made at the NARF unit scheduled for future survey.

WORDIE H. PARR, Ph.D.

Captain AUSTIN. Our next witness is Mr. Mitchell.

Mr. MITCHELL. Mr. Chairman, on behalf of the U.S. Air Force, I am honored to appear before you today to present a brief summary of the current research and future plans of the Air Force radiofrequency radiation bioeffects research program.

This research program has been active at the School of Aerospace Medicine since 1968. It is responsive to specific Air Force systems requirements and to the development of an Air Force radiofrequency radiation health hazards control program as documented in Air Force Regulation 161–42.

The ongoing research is an integral part of a coordinated triservice program under the Director of Defense Research and Engineering. It is closely integrated with the other services at the working level and with many other civilian research institutions via annual reports to the Office of Telecommunications Policy, participation in national scientific meetings, and open publications in professional journals.

Some examples of our Air Force program accomplishments and contributions are described in my written testimony that has previously been provided.

One of our major contributions and the continuing thrust of our present program is a series of studies to describe how radiofrequency radiation is distributed in biological organisms. These studies show conclusively that the effect of RF radiation on biological systems is dependent not only on the magnitude of the exposure level but also on the frequency of the radiated energy as well as the size and orientation of the organisms in relation to the emitter.

Such studies are an absolute prerequisite to an understanding of the basic coupling mechanisms by which RF radiation interacts with biological systems. While much knowledge has been accumulated, the biological consequences of RF radiation exposure are still sufficiently complex that the real world impact on man's state of health may not be known for several years.

The vast majority of today's reported radiation induced biological effects describe an effect in animals without adequate consideration for extrapolating such effects to humans.

The RF radiation effects observed in animals as a result of laboratory studies must be carefully extrapolated to effects on humans and with due regard for radiation frequency as well as species' differences.

Figure 4 in the written testimony depicts typical power absorption scaling factors to be used when extrapolating effects observed in rodents to predicted effects in man.

Furthermore, the distribution of such power and the species' physiological response must also be considered in the complex real world situation. Frequency scaling to establish equivalent RF radiation absorption is gaining more and more acceptance throughout the research community and thus plays a dominant role in how one assesses current scientific data.

RF radiation energy distribution and measurement is still the priority one research requirement of the triservice DOD program.

In response to this requirement, the Air Force has undertaken a multiyear program to develop and update a radiofrequency radiation dosimetry handbook for the use of all investigators. The first edition of the handbook was prepared under Air Force contract with the University of Utah and published as a School of Aerospace Medicine Technical Report in September of 1976.

More than 300 copies have been distributed to researchers in the United States and Europe. The initial response is very favorable and many of the calculated curves are now being experimentally validated. A follow-on program will seek out suggested improvements in the handbook's content and use. Additional test data are being actively solicited for inclusion in the next edition which is scheduled for publication in early 1978.

This effort should provide the necessary link between biological effects observed in irradiated animals and corresponding effects which could occur in man.

The fact that RF radiation induced biological effects are frequency dependent suggests that a safety criteria should be promulgated based upon a frequency dependent approach. In support of this philosophy, the Air Force developed and published its current regulation in November of 1975.

On the basis of relative power absorption, this regulation allows a slightly higher frequency dependent exposure level for the 10 kilohertz to 10 megahertz portion of the RF spectrum where no previous standard existed. Otherwise, it is consistent with the OSHA standard which covers the frequency range from 10 megahertz to 100 gigahertz.

Figure 5 compares our Air Force exposure standard with other standards—actual and proposed—and also to a calculated curve showing the relative power absorption for man normalized to 10 mW/cm^2 absorption at 70 megahertz.

While the U.S. and U.S.S.R. standards differ by a factor of 1,000 over the frequency range, 50 megahertz to 300 gigahertz, it is important to note that the U.S.S.R. applies frequency dependent modifiers to increase their permissible exposure levels below 50 megahertz.

Considerable progress has been achieved toward the understanding of radiation absorption and distribution in biological systems and the methodology for extrapolating such information to humans in real world situations appears near at hand.

Air Force future efforts are being directed to refine hazard assessments for a wider range of operational situations and for new systems involving phased array technology. To this end we are acquiring a nationally unique exposure facility to investigate these types of radiations.

In recognition of the national and international controversy concerning the biological effects of radiofrequency radiation, the Air Force has significantly increased its research commitment in this area. Planned efforts will systematically define the biologic significance of radiofrequency radiation exposure of interest to the Air Force and the populace surrounding our facilities.

Effects on the central nervous system, immune system, and behavior, which are important in the current controversy, will continue to be highlighted in our future programs.

The end result of such studies must be a comprehensive assessment of clinical findings and a judgment as to their significance. Future standards must be based on the results of well defined, replicated studies that clearly demonstrate that the effects are detrimental to human health or performance and that they do not represent transient or inconsequential phenomena from which there is always complete recovery.

In summary, the Air Force radiofrequency radiation research program is totally dedicated to personnel safety as a first priority but with a proper and reasonable balance against unnecessary operational constraints.

[The statement follows:]

STATEMENT OF MR. JOHN C. MITCHELL[1]

UNITED STATES AIR FORCE RADIOFREQUENCY RADIATION BIOEFFECTS RESEARCH PROGRAM

Radiofrequency radiation (RFR) is defined herein as that portion of the electromagnetic spectrum between 10 kilohertz and 300 gigahertz, and includes "radio-waves" and "microwaves" (Figure 1). It is also described as nonionizing radiation.

The Air Force RFR research program is conducted in the Radiation Sciences Division of the School of Aerospace Medicine (SAM) at Brooks AFB, Texas. The School is located within the organizational structure of the Aerospace Medical Division (AMD) of the Air Force Systems Command (AFSC).

During the period 1968 to 1972 the Air Force program was structured to evaluate the biological effects of 3 to 30 megahertz radiation exposures in support of the Over-the-Horizon Radars (441A and 414L systems). The Research and Development program was primarily "reactive" to specific systems requirements and Air Force user needs. In the period 1972–1974, a long range research plan was formulated and coordinated with the U.S. Army and Navy in a tri-service effort (Biomedical Technology Coordination Plan). More recently (1974–

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[1] Radiation Sciences Division, USAF School of Aerospace Medicine, Brooks Air Force Base, Tex.

1976), a comprehensive triservice program for biomedical research of electromagnetic (radiofrequency) radiation effects was developed at the request of the Office of the Director of Defense Research and Engineering. The ongoing Air Force program is an integral part of the triservice program under DDR&E. It is closely coordinated with the other Services at the working level and with other research institutions via annual reports to the Office of Telecommunications Policy—Electromagnetic Radiation Management Advisory Council (OTP–ERMAC).

Program accomplishments to date include (Figure 2):

(1) Development and operational implementation of a unique (one-of-a-kind) RFR exposure system to study the biological effects of 10–30 megahertz radiation. The system was used to establish the RFR safety criteria for the over-the-horizon backscatter radar.

(2) Development of special laboratory tools to measure RFR exposures. Under Air Force sponsorship, the National Bureau of Standards, Boulder, Colorado, developed a series of electric- and magnetic-field probes, a differential power absorption measurement system, and a "near-field" radiation simulator. These tools were used to validate important theoretical calculations concerning the frequency dependent aspects of 10–30 megahertz RFR exposures.

(3) Laboratory and field tests to assess the effects of RFR fields on cardiac pacemakers. About 1970, it was recognized that some cardiac pacemakers could be seriously disrupted by pulsed RFR fields. A series of tests was performed to establish the relative sensitivities of the marketed devices. These test results were provided to the cardiac pacemaker manufacturers, to the Food and Drug Administration, and to the Air Force Surgeon General along with recommendations that a 200 volt per meter (V/m) performance standard be adopted. Subsequent actions by the pacemaker manufacturers essentially resolved the interference problem. In 1970 only about 20 percent of the marketed pacemakers would meet the 200 V/m criteria, while today more than 90 percent of the marketed devices meet the 200 V/m criteria; many of them having much higher safety thresholds.

(4) Establishment of a Radiofrequency Radiation Health Hazards Control Program (documented in AFR 161–42, Nov 1975). This regulation establishes policies, assigns responsibilities, provides RFR exposure standards, and establishes a surveillance program for the protection of personnel working with or in the vicinity of RFR emitters.

(5) Development under Air Force contract of picosecond optical range-gating techniques for use in diagnosing eye injuries. The prototype system is being used to study RFR induced cataracts.

(6) Publication of the first edition of an RFR dosimetry handbook (SAM–TR–76–35).

Current research program

The USAF radiofrequency radiation research program supports new RFR surveillance systems development, and is comprised of contractual and in-house efforts in a ratio of about 65 percent and 35 percent respectively. It includes studies of: (1) RFR power absorption, distribution and measurement, (2) effects on the central nervous system, (3) effect on immune systems, (4) cellular level effects, (5) medical device interference, (6) the effect of fractionated (long-term) exposures, (7) effect of combined stress, and (8) the effects on behavior (Figure 3). More recent efforts are directed to the study of the specific biological consequences of man's exposure to a variety of pulsed RFR fields relative to continuous wave exposure.

The vast majority of reported RFR induced bioeffects describe the effect in animals without adequate extrapolation to these effects in humans. RFR induced bioeffects observed in animals must be carefully extrapolated to effects in humans with due regard for size effects, frequency dependency of dielectric constants and conductivities, and field polarization, as well as species biological differences. Figure 4 depicts typical power absorption curves for prolate spheroid models of man and rodents (E-field polarization). The concept of frequency scaling to establish equivalent RFR power density absorption is gaining acceptance throughout the research community.

As a part of the triservice priority one effort (Energy Distribution and Measurement), the Air Force has undertaken a multi-year program to develop an RFR Dosimetry Handbook. The first edition of the handbook was prepared under Air Force contract by the University of Utah and published as USAF School of Aerospace Medicine Technical Report 76–35 in September 1976. More than 300 copies have been distributed to researchers in the United States and Europe. Initial response concerning the acceptance and use of this handbook is very favorable. Many of the calculated curves are being experimentally validated. A follow-on program will seek out suggested improvements in the handbook's content and use. Furthermore, additional test data are being actively solicited for inclusion in the next edition (scheduled for publication early in 1978). In the final analysis, this effort should provide the necessary link between biological effects observed in irradiated animals and corresponding effects which might occur in man.

The fact that RFR induced biological effects are frequency dependent suggests that safety criteria could best be promulgated using a frequency dependent approach. In support of this philosophy, the Air Force developed and published a new regulation in November 1975, viz, AFR 161–42, Radiofrequency Radiation Health Hazards Control. On the basis of relative RFR power absorption, it incorporates a slightly higher frequency dependent exposure level for the 10 kilohertz to 10 megahertz portion of the FR spectrum, where no previous standard existed. It remains consistent with OSHA Standard 29 CFR 1910.97, which covers the frequency range from 10 megahertz to 100 gigahertz. This new safety standard which defines a complete RFR hazards control program has been accepted throughout the Air Force and has been implemented by all major commands, since it provides detailed guidance on the application of PELs (permissible exposure limits) across the frequency range of Air Force RFR emitters.

Figure 5 compares the Air Force RFR exposure standard to several other standards (actual and proposed) and to a calculated curve showing the relative power absorption for man normalized to 10 mW/cm^2 absorption at 70 megahertz. While the U.S. and USSR standards differ by a factor of 1000 over the range 50 megahertz to 300 gigahertz, it is important to note that the USSR applies frequency dependent modifiers to increase their permissible exposure levels below 50 megahertz.

Follow-on research studies in support of 10–30 megahertz RFR emitters (principally the OTH–B radar) are essentially complete. Power absorption studies were completed for the 10–50 megahertz frequency band using monkeys, prolate spheroid and ellipsoid models, and the data are compared with theoretical calculations. Primate temperature profiles, as a function of incident power densities and time, were completed for three HF band frequencies (15, 20, 26 megahertz). Power densities ranged from 500 to 1500 mW/cm^2 and exposure times from 0.5 to 6 hours. The previous studies on the effects of HF band radiation on rodent growth and development by SAM and its contractors were reevaluated. These research findings were published in a series of SAM technical reports and in open press technical journals (references attached). Air Force program interests are now being redirected to verify the adequacy of existing standards for the new phased array radar systems having unique pulse characteristics. RFR fields in the frequency range from 400 megahertz to 10,000 megahertz will be evaluated.

Air Force contractual efforts in support of the triservice ocular effects program resulted in the development of a system for noninvasive optical evaluation of RFR induced eye abnormalities. A follow-on contract was awarded to conduct bioeffects studies to evaluate the utility of the completed system. Pending successful validation, this new research tool may be applied to objectively quantitate possible effects of RFR induced eye injury in a series of experiments ranging from acute to long term exposures. It will also provide a permanent record for comparative purposes.

In order to study mechanisms of injury at the cellular and subcellular levels and perhaps reduce the use of animal experimentation, a specialized exposure system for irradiating cell cultures to broadband RF fields under controlled field and temperature conditions was developed under Air Force contract with the University of Washington. The system produces a relatively uniform electric field strength up to 10,000 volts per meter for a 5 millimeter sample of culture medium. Preliminary experimental results have been reported. Additional research is in progress.

Microwave inactivation techniques developed under Air Force sponsorship were used in four distinct and separate studies of RF radiation induced central nervous system effects. Mice were exposed to 19 megahertz using a "near-field" radiation simulator to determine if such radiation alters the whole brain level of: (1) serotonin or its metabolite 5-hydroxyindole acetic acid; and/or (2) norepinephrine. Other studies were completed for rates exposed to 1600 megahertz fields. Additionally, metal ion concentrations in specific areas of the rat brain were evaluated after 1600 megahertz exposures.

Recent reports in the literature have indicated changes in the permeability of the blood-brain barrier after exposure to microwaves. Because of the safety implications of these reports, attempts were made to replicate one of the investigations. In the reported study, 1200 megahertz radiation pulsed at a low peak power density (2 mW/cm^2) was reported to increase the permeability of the blood-brain barrier to sodium fluorescein. In the USAFSAM replication, fluorescence due to sodium fluorescein in the brain substance of irradiated rats was not observed at the peak power reported in the original investigation. The study was extended to include chemical assay of sodium fluorescein in various areas of the brain. At a peak power of 2 mW/cm^2 no increase in the brain concentration of sodium fluorescein was noted. However, at a peak power of 75 mW/cm^2 (37.5 mW/cm^2 average) the fluorescein content was significantly increased as compared to controls. At this higher peak power level brain temperature was increased about 4° C. Further research is being carried out to establish a threshold for the increased fluorescein content. Additional studies will be initiated using radiolabeled compounds that do not normally cross the blood-brain barrier. This work suggests the importance of independent laboratory replication of all important research findings.

A series of experiments was conducted to investigate the effects of RFR heating on cell-mediated immune defense mechanisms. RFR heating effects, as determined by inflammation and/or the number of peripheral blood and spleen lymphocytes, were followed in rodents exposed to 26 megahertz radiation (3° C increase in core temperature), 5 megahertz (no measurable increase), and warm-air treatment (3° C increase). RFR heating (2 megahertz) decreased sheep red blood cell-induced inflammatory footpad swelling by 45 percent over that observed in warm-air or sham control animals. The suppression of inflammatory response was accompanied by a well-defined, transient four-fold decrease in lymphocytes and increase in neutrophils maximal at 3 hours post-exposure. Normal blood lymphocyte and neutrophil levels were reestablished by 92 hours post-exposure. Triple exposure to 26 megahertz radiation at 3-hour intervals achieved a marked, but transient lymphopenia and neutrophilia sustained over a 12-hour period; all animals reverted to normal levels by 92 hours after the final exposure. Time course of this lymphocyte response closely follows glucocorticoid-induced lymphopenia and suggests that RFR heating is perceived as a simple stress phenomenon accompanied by steroid release. In addition, percentage of B-lymphocytes in the spleens of RFR heated mice was two-fold greater than that obsedved in RFR nonheated, warm-air, or sham treated animals. That RFR heating induced an arrest in B-cell splenic traffic resulting in apparent pooling of B-lymphocytes in the spleen, in addition to suppression of inflammatory response and lymphopenia, suggests that cell-mediated immunocompetence may be altered in these animals after significant RFR heating takes place.

Future plans

Considerable progress has been achieved concerning the understanding of RFR power absorption and distribution in biological subjects and the methodology for extrapolating to humans in real world situations now appears near at hand. Air Force efforts are being redirected to refine RFR hazard assessments for a wide range of operational situations and new systems. The principal Air Force research needs, which include the evolving phased array technology, are documented in Required Operational Capability 3–76 and address the following (Figure 6):

(1) Assess the relative biological consequences of man's exposure to pulsed versus continuous wave RFR fields including Air Force relevant modulation patterns such as those associated with PAVE PAWS, the E3A, COBRA DANE, and the Joint Surveillance Systems Program. Acquisition of a peak pulse power simulator has been initiated to support this task. Laboratory studies will include examination of the effect(s) of RFR on the central nervous system, immune response, and behavior.

(2) Identify clinically significant biological response thresholds for acute RFR exposure of man in terms of the animal model used, exposure conditions, specific absorption rates (SAR), temperature change, and extrapolation/scaling factors used.

(3) Identify biophysical mechanisms that could produce a clinically significant biologic effect as a result of long term/chronic, or fractionated RFR exposures. Conduct studies to assess the significant effect(s) of such exposures.

(4) Quantitate the ratio of peak to average power absorption (hot spots) in experimental animals for worst case exposure conditions, extrapolate to equivalent situations in man and assess the real time distribution of this power via the body's thermoregulatory system.

(5) Establish the relative biological effect and clinical significance of partial versus whole body RFR exposures. Examination of the application and effect of diathermy treatments may yield important data.

The frequency dependent aspects of RFR power absorption and distribution in man must be carefully considered if one is to establish meaningful safety standards. For example: (1) in the frequency range 10 kilohertz to 10 megahertz, where the human is small compared to the wavelength of the incident radiation, scaling may be accomplished on the basis of total power absorption calculations assuming simple shapes; (2) in the frequency range 10 megahertz to 500 megahertz where the human subject (small child to large man) approaches resonant conditions, scaling may be accomplished by assuming equal capture apertures for the man and animal, i.e., by scaling to the frequency which results in the same wavelength to subject length ratio and then applying relative specific absorption rates (such as those documented in the RFR Dosimetry Handbook, SAM-TR-76-35); and (3) in the frequency range 0.5 to 100 gigahertz where the human subject becomes large compared to the wavelength of the incident radiation, scaling may be accomplished by selecting the animal exposure frequency that will give the equivalent ratio of radiated to nonradiated volume as may be expected in the human subject.

The potential enhancement of power absorption in man when he is in electrical contact with the ground, requires that empirical studies be conducted to establish the degree of grounding likely under a wide range of environmental situations.

Controversy will continue concerning the potential "nonthermal" versus "thermal" effects of RFR exposure. The clinical significance of such effects, in the absence of a measurable temperature change, must be carefully documented, and a damage mechanism defined.

Appropriate modifiers to account for environmental conditions (temperature humidity index) and state of health of the person potentially at risk should be developed.

RFR exposures of humans in "real world" situations do not conform to the static uniform field conditions normally used in laboratory studies. Most human exposures occur at very low levels (less than 0.001 mW/cm^2) under conditions where the movement of the irradiated subject and/or the RFR source create a dynamic situation. Exposures that approach 10 mW/cm^2 almost always occur in occupational situations where the subject is sufficiently close to the RFR source that the actual exposures that approach 10 mW/cm^2 are often partial body exposures rather than whole body.

Discussions concerning RFR safety standards correctly stress worst case conditions such as the power absorption level at resonance and other enhancements such as electrical grounding. While fully endorsing the worst case philosophy in standard setting, care must be exercised to avoid establishing a standard against a worst case instance which has negligible likelihood of occurring in the "real world."

The Air Force RFR research program is fully dedicated to personnel safety as the first priority, but with proper and reasonable balance against unnecessary operational restraint.

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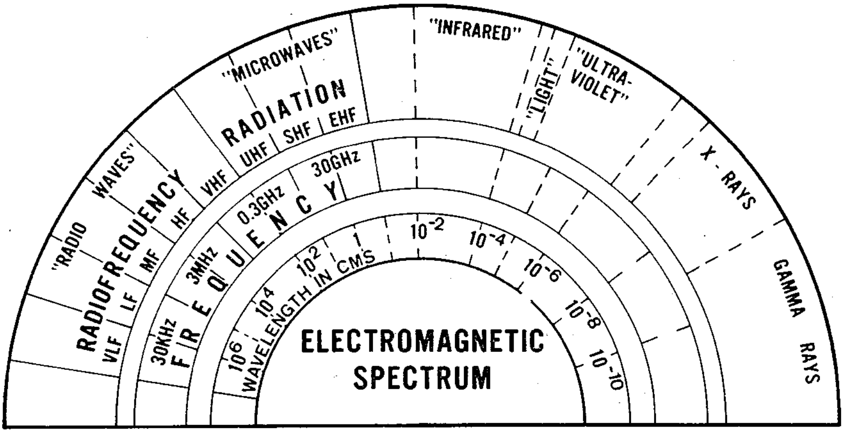
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"ULTRA-VIOLET"
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WAVELENGTH IN CMS
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ELECTROMAGNETIC SPECTRUM

Figure 1

Figure 2.—USAF RFR Program Accomplishments

1. Developed a unique 10–30 MHz RFR exposure system and conducted studies to establish RFR safety criteria for the OTH–B radar (1970–72).
2. Developed laboratory tools to measure 10–30 MHz RFR fields and power absorption (1971–73).
3. Conducted studies to resolve potential adverse interactions between RFR emitters and cardiac pacemakers (1971–74).
4. Established a RFR health hazards control program—AFR 161–42, AFOSH standard 161–9 (1975).
5. Developed a prototype system to quantitate RFR induced eye injury (1976).
6. Published a RFR dosimetry handbook (SAM–TR–76–35, 1976).

Figure 3.—Current USAF RFR Bioeffects Research Program

Primary studies address RFR effects on central nervous system, effects on the immune system, and effects on behavior.

Objective: Assess the biological response and clinical significance of man's exposure to air force RFR emitters.

Approach: Quantitate RFR power absorption and distribution in biological specimens. Correlate with the biological response and extrapolate to man equivalent exposures in real world situations.

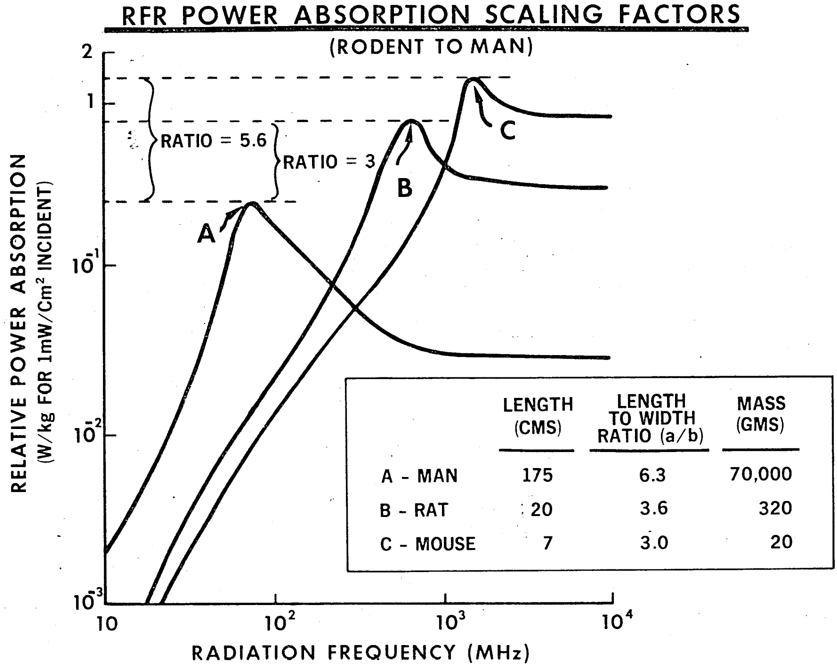

FIGURE 4

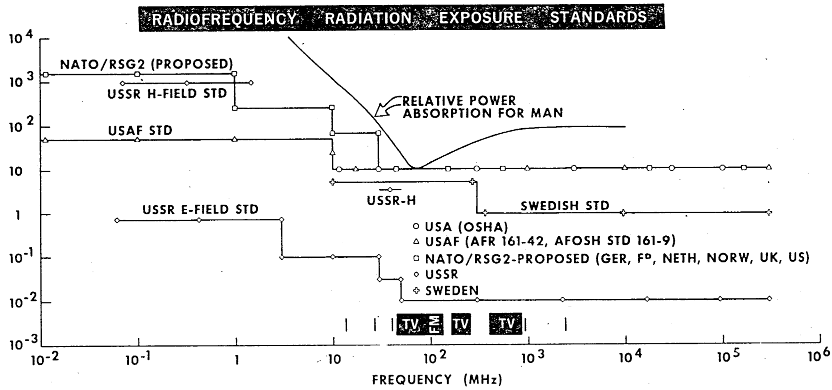

FIGURE 5

Figure 6.—USAF RFR Bioeffects Research Program, Future Plans/Research Needs, Using Air Force System Specific Parameters

Assess relative consequences of pulsed versus continuous wave exposures.

Identify clinically significant biological response thresholds for acute exposure and extrapolate to man.

Identify possible biophysical mechanisms that could produce clinically significant long term effect.

Quantitate "hot spots" and assess significance in terms of thermoregulatory response.

Establish clinical significance of partial versus whole body exposures.

Establish effect of long term fractionated exposures.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND ANSWERS THERETO

Question 1. During your testimony you described radio frequency radiation effects on "cell mediated immune defense mechanisms," such as decreased inflammation and lymphocyte count. If these effects occurred in humans, what would be the observable effects? Would this render a person more susceptible to disease?

Answer. Testimony given to the Committee described possible effects of radiofrequency radiation on cell-mediated defense mechanisms in the rodent. The studies to investigate impairment of immune function are in progress. As a result, radiofrequency effects on disease susceptibility, with regard to the immune system, are not characterized in the rodent as yet. Without data from at least one model system, i.e., the rodent, the extrapolated case for man cannot be characterized with certainty.

Question 2. You suggested that radiation is preceived as a "simple stress phenomenon accompanied by steroid release." Since steroids are a type of hormone, does this mean that microwaves could affect the emotions?

Answer. Investigations show that only microwaves of sufficient intensity to produce a heat load act as a stress in the rodent. Steroid release due to stress is a biological response to help an animal adapt. In general ("Stress in Health & Disease," H. Selye, Butterworths, Boston, 1976), the emotional state is characterized as more alert, highly responsive, more demonstrative, and possessing heightened awareness and perception.

Senator FORD. Captain Austin, I have a few questions about Project Pandora, if I may. I did not receive complete answers from the previous witness. Let me ask this question. Why was the project classified?

Captain AUSTIN. Well, sir, I would like to ask Dr. Larsen to address that. A lot of this work was done in the Army. He can address some of that.

Senator FORD. Dr. Larsen, can you respond to that question?

Major LARSEN. Mr. Chairman, I would like to preface my remarks on the basis that the Pandora project was done at the Walter Reed Army Institute of Research under ARPA guidance. Microwave research was not acquired by the Surgeon General of the Army until 1971. So, the period in which these events took place is one on which the Army Surgeon General was not directly involved.

I was present at the Institute in 1970 when Project Pandora was winding down. In terms of your original question, why was the project classified, I can honestly say that I can't answer that question.

Senator FORD. Who should we ask the question of?

Major LARSEN. ARPA, sir, I would suggest.

Senator FORD. I guess we will ask them.

Since you were in on the winding down or the closing out of the project, can you tell me how much it cost?

Major LARSEN. In terms of capital investment, my understanding is that the facilities cost was in the neighborhood of $2½ million, that the additional expenses on top of that in terms of contracts and so forth were in the neighborhood of another $200,000 to $300,000.

Senator FORD. Roughly $3 million?

Major LARSEN. I would say so, sir. That's a very rough estimate, though, Mr. Chairman.

Senator FORD. Would it be in the ball park?

Major LARSEN. Yes, sir, I believe it would.

Senator FORD. Why were major reports containing useful technical content—I am going to use the word—"destroyed." The committee's report is available but the technical data is not available.

Major LARSEN. Well, sir, I can't answer that question fully. I can say that some results from that study were removed from the building at the time that I was first present; namely, in the period of 1970. I knew that those reports were removed, but I didn't know their fate. I understand from what has happened that they were destroyed, but I have no direct personal knowledge other than the fact I witnessed them being removed.

Senator FORD. Any particular reason?

Major LARSEN. Well, sir, I think that it was a question of things rolling off the end of the time frame, where documents were outlived rather than anything else. That is just a guess.

Senator FORD. Captain Austin, Dr. Perry has written a response to the committee's questions stating that the Defense Department has a high degree of awareness to the potential health hazard associated with the development of weapons systems that emit electromagnetic radiation.

What are the potential health hazards he was alluding to?

Captain AUSTIN. We discussed many of them today, Mr. Chairman.

Senator FORD. Give me a laundry list.

Captain AUSTIN. I don't know whether a laundry list would be a very good term to use.

Senator FORD. The first witness gave us that term. I am beginning to think the information is laundered before it is passed on to somebody else.

Captain AUSTIN. All of the research that we are doing is looking for some sort of bioeffects. I think that I would sum it up to say that we have not found any bioeffects at the levels where the standards are now set.

So, we are looking—doing experiments to look at very low levels. We are looking at new pulse waves and various other modes of transmission. And sort of on a treasure hunt, if you will.

The potential effects obviously have been discussed here by the various people, the cataracts at very high levels of radiation can be caused in animals. I suppose there is—obviously most of the effects are due to direct heat like the oven that was mentioned before. These levels are caused at such extreme levels of radiation that they are way above what we would see in the environment today.

Senator FORD. Well, the heat was mentioned a few moments ago, 35° Celsius.

Captain AUSTIN. 45°.

Senator FORD. 45°?

Captain AUSTIN. That was measured in the lens itself when measured inside the lens.

Senator FORD. How hot is 45° Celsius?

Captain AUSTIN. 113° Fahrenheit. It is very hot. It must be recognized that that is inside the eye and that would be—if you tried to do that with heat itself, it would be a very hot environment. It focuses, of course—these rays, that's the problem as mentioned by Dr. Larsen. The rays focus inside——

Senator FORD. Is there any classified research being done at DOD?

Captain AUSTIN. Absolutely no classified medical research on EMR is being done in the military departments that we are aware of at this time. We do not have any. We have declassified all of the past bioeffects medical research done in this area. It may be necessary to perform some future classified research to develop appropriate defensive measures to counter potential adversary systems.

Senator FORD. Now that the military was in large part responsible for the adoption of the 10 milliwatt per square centimeter exposure standard, are you still satisfied with that standard?

Captain AUSTIN. Yes, sir. At the present time we are.

Senator FORD. I think—is it true—you might correct me on this—the Canadians have lowered their standard and several commentators have suggested further refinement such as including a time factor for exposure.

Captain AUSTIN. Yes, sir. I think that is true. There is a proposed NATO standards. Mr. John Mitchell in his chart No. 5 showed how standards presently existing have been modified or are proposed to be modified based on frequency changes.

Senator FORD. Is DOD doing anything to review or assess the 10 milliwatt standard?

Captain AUSTIN. We don't see any reason to change it at this time, sir. We don't see any reason to change the standard up or down at this time from our research.

Senator FORD. Dr. Perry also directed the committee's attention to a lack of consistency in standards proposed by the regulatory agencies noting that, and I quote:

> There is a growing tendency amongst the agencies controlling radiation hazards to propose standards in the absence of reproducible scientific data demonstrating clinically significant effects or reliable epidemiological data that suggest that the current standards are not safe.

What agencies and proposed standards was he referring to?

Captain TYLER. I think some of this you heard last week. Some of the proposals come from EPA. They have gone to the Federal agencies and asked for a member to work with them on this. Again there were two proposals, about 2 to 3 years ago, by OSHA. They were requested to set a standard for EMP, or electromagnetic pulses by the Boeing Co. They asked for comments on this.

Again, several Federal agencies provided comments. OSHA made the ruling that there were less than 200 people exposed to this area, therefore, they saw no need to issue a standard at that time. They also proposed a standard for telecommunications workers which effectively set a 1 milliwatt standard for microwave exposure in contrast to their microwave standard of 10 milliwatts.

Again, this was commented on by several Federal agencies including NIOSH who is supposed to be their scientific consultants. Following receipt of the comments they dropped this from their proposal.

Senator FORD. Since you have the microphone, I will ask you another question.

All of the services in my opinion pay lip service to the effective coordinating role being played by ERMAC and OTP and the Tri-Service Committee, but the committee notes that despite this coordination, there appears to us to be considerable overlap in research, in the research effort.

Can you clarify this point for me and comment on the coordination between the services?

Captain Tyler. One, I really don't think there is overlap. It has been pointed out that there is a tremendous number of frequencies to be used. There is a tremendous number of various parameters. If three or four people are looking at cataracts, which we have had in the past, one group will be using one frequency, another group will be using another frequency, and try to compare these two results.

Likewise, there has been a real hesitancy in the scientific community when one investigator reports a finding, and the other investigators in the scientific community say, well, who has repeated this experiment? It is a single experiment with a certain group of animals. You would like to have repeatability by different laboratories and different investigators confirm the result as a positive finding.

One classic example that I pointed out was the permeability of the blood brain barrier. This was originally reported by an investigator from a private laboratory using fluorescent dye techniques in the brain. The blood brain barrier was again used by another investigator working toward his Ph. D. degree, who used the facilities at Walter Reed as his exposures. He used radioactive isotopes. Again, a private university contractor also using the Walter Reed facility because of the limited facilities, looked at the blood brain barrier from a histological standpoint. All three of these investigators confirmed that there were some alterations in the blood brain barrier.

I think you could say that now it is more widely accepted by many people. Each study was not duplicative in itself, although they were studying the same effect.

Senator Ford. Suppose they were studying different intensities and different functions, wouldn't it be better to put them together so if one finding related to another they could all look at it, rather than comparing?

I am not a researcher. It is a foreign field. It seems to me if you are working on cataracts, and you have the research spread in ten different locations, if you had the research on cataracts in one location, anything that might relate would be known immediately.

Captain Tyler. I think one of the problems of researchers—not panning researchers in general, but we all have our own individual biases.

Senator Ford. No kidding?

Captain Tyler. If you have three or four researchers see the same effect, and they are all from the same group, we could have the same group of biases entering into whatever research was going on. But, when you have various different groups doing research in the same area, each group may have a different bias or look at it a different way. Thus, you can overcome this bias. Whereas, if it was only in one group, you could certainly have consistency of the biases.

Senator Ford. ERMAC and OTP's functions may be transferred out of the White House under the EOP reorganization. How might this impact upon coordinating the research activities you have been talking about?

Captain Tyler. I really don't know, sir. Certainly within the Tri-Service, it would have no impact. In my personal opinion, I think it will make it more difficult for the various agencies to keep as close a working relationship as we have at the present time. The coordination function must be above the individual agency level.

Senator FORD. Can you speculate on why the Canadians lowered their standards? They have a proposal out from one group that proposed a 1-milliwatt standard. This is the latest information that I have. I am not aware as yet that the new standard has been adopted.

Senator FORD. Do you know why they would be doing this?

Captain TYLER. No, sir. I don't.

Senator FORD. Are they smarter than we are?

Captain TYLER. No; I don't think so. In fact, we have been doing some coordination. I happen to be chairman of a NATO committee looking at this. Certainly the Canadian members on the NATO committee are still in concurrence that a 10 milliwatt standard is safe at the present time. So, I don't know why the Canadians are proposing a new standard.

Mr. MITCHELL. I would like to comment on that. I think Dr. Tyler is right that the Canadians do not have an official standard yet. However, there have been several proposed. One of the ones that I have seen does show a frequency dependent standard much as shown in figure 5 of my written testimony. They have recommended lowering it slightly just in the resonance range for man—with a difference of 20 to 200 meghertz, which is a very narrow part of the frequency spectrum. This follows closely the dip of the curve shown on figure 5 in my written testimony. They, too, are looking at the scientific aspects of what we see in our research today and are trying to apply that in a more meaningful way.

Senator FORD. Let me ask you something, Captain Austin. Can you speculate on why the Russians would want to irradiate the U.S. Embassy in Moscow with microwaves?

Captain AUSTIN. No, sir, I cannot.

Senator FORD. You couldn't speculate?

Captain AUSTIN. No, sir.

Senator FORD. I want to see if you can give me some other information on an issue that is in the news. There has been considerable discussion of the so-called neutron bomb, as being developed by and for military application. As I understand it, and from just reading the paper and other sources of information available, the warhead is designed to kill human beings via an exceedingly high pulse of ionizing radiation of about 8,000 to 10,000 rads. Any human exposed to this level of radiation would be quickly incapacitated and soon die. What is known about the effects of the neutron warhead on those humans who do not receive lethal exposure? Have tests been conducted to determine the bomb's effect on survivors of the initial radiation?

Captain AUSTIN. Well, sir, in the ionizing radiation area, we have done a number of tests to determine what the effects would be. In the basic research that has been done, I think we could calculate what those effects would be.

I don't know whether there is any necessity to check a specific one for this weapon.

What I have read in the newspapers, too, is mostly what I know about it.

Senator FORD. We are going to ask the same question of ERDA tomorrow.

Captain AUSTIN. I understand, and I think it is valid, that this is the same thing we have had in nuclear weapons before.

Augmented, if you will, to reduce—increase the radiation, reduce the explosive effect. That's about the way it looks to me.

Senator FORD. Let's talk about that a little more then.

More specifically, how far out from the point of the warheads exactly is a level of 20 rads maintained?

Captain AUSTIN. I do not know, sir.

Senator FORD. Do either one of you know?

[No response.]

Senator FORD. None of you have been involved in any type of study relating to ionizing radiation with respect to the neutron bomb?

Captain AUSTIN. No, sir. We centralize our radiation efforts in another agency.

Senator FORD. You have no knowledge of it at all?

Captain AUSTIN. Only basic medical knowledge, sir.

Senator FORD. That makes you an expert, doesn't it?

Captain AUSTIN. I didn't bring my ionizing radiation briefcase today.

Senator FORD. Maybe we will get that out for you.

Major Larsen, what combat technology in nonionizing radiation is emerging that could have a significant impact on the civilian sector?

Major LARSEN. Could I ask for a clarification on that question, sir? Do you mean in the sense of hazards?

Senator FORD. In your statement, you, I believe, alluded to the potential hazard to the health and safety of Army personnel, as well as to the general population, to quote you, "from future Army uses of microwave radiation." Without compromising security can you elaborate on what you mean by this phase?

Major LARSEN. Yes, sir. I think we were addressing the fact that electronic warfare and electronic countermeasures are going to increase the rate at which Army systems are developed. This means novel spectrum utilization, and it means combining many frequencies and many characteristics of radiation. We don't anticipate that this would affect the general population. Instead, sir, what we were speaking of was the situation in the battlefield where soldiers would be exposed to a combination of electromagnetic radiations from our own equipment and from equipment of adversary forces.

Senator FORD. You mentioned that your research is augmented toward biological and psychological effects on man. Could you elaborate a little more on what you mean by the psychological aspects?

Major LARSEN. Well, sir, what we have in mind there is the effects, behavioral effects that have been reported in laboratory animals. These relate to the question of seizure susceptibility and brain blood alterations in men.

The question of seizure susceptibility is one raised by the Polish research which has suggested that certain forms of radiation caused guards to have seizures and things of that sort.

We have not been able to confirm those findings.

We have used animals which already have a propensity for seizures. We find that microwave exposure only has a transient effect on seizure susceptibility. This transient effect is one of decreasing threshold, but that with continued exposure, the effect goes away.

In terms of the blood brain barrier, laboratory animal studies have taken place.

We also have convened an expert group of civilian senior scientists to advise us on the direction of future research in the studies of membrane permeability alteration. The recommendations of that panel are included in the written part of the testimony.

To highlight it, it consists basically of studies in more simplified systems such as membrane preparations, rather than studies at the level of whole animals. Certainly whole animals are a part of it, but it is not the major part of the study.

Senator FORD. In your testimony you say that pulsed microwaves directed to a solid nonliving object can cause the object to emit sound.

Major LARSEN. That's right, sir.

Senator FORD. Then, you go on to discuss human hearing of microwaves and Eastern bloc experiments with "animals susceptible to fits from other causes."

Major LARSEN. Right.

Senator FORD. Is the implication here that the Eastern bloc research on microwaves is actively directed toward altering nervous system functions from a weapon's point of view?

Major LARSEN. I can't answer that question, sir.

My orientation in this matter is that of a physician. I am not privy to information on weapons development.

Senator FORD. I will get back to the questions.

Who could I ask that would know?

Major LARSEN. Would know about weapons development, sir?

Senator FORD. Yes, sir, central nervous system functions, from a weapons point of view.

Major LARSEN. I believe, sir, the appropriate command is known as DARCOM.

Senator FORD. What?

Major LARSEN. DARCOM. D-A-R-C-O-M. It is the U.S. Army Development and Readiness Command.

Senator FORD. Your report——

Major LARSEN. I might interject that on the basis of my own personal information and on the basis of what those of us at the table know, we are not—the United States is not developing any directed energy microwave weapons. As I say, the definitive answer to that question should come from elsewhere.

Senator FORD. Your report about behavioral studies of rats exposed to pulsed microwaves exhibiting aversive behavior sounds very interesting. What implications with proper scaling does this have for human beings?

Major LARSEN. It might indicate that human beings might find certain microwave environments to be unpleasant in ways that are rather vague. The conditioned aversion experiment we described in the testimony is a sensitive behavioral test for properties of radiation, whether it is ionizing or nonionizing, where the exact mechanism of action is unknown or widely distributed.

The implications, you asked for humans, would be that they would find the environment to be unpleasant. I think an analogy might be, for example, office workers who find that they are particularly tired after spending time in offices that have lots of subsonic sounds. It is not something that you would directly perceive, but it is something that would affect your perception of pleasantness or the unpleasantness of the environment.

Senator FORD. From the Army's retrospective study, was any sort of significant association found between occupational microwave exposure and cataracts?

Major LARSEN. No, sir, none that I know about.

Senator FORD. What was the range of values of the exposure?

Major LARSEN. A very wide range, sir. The people selected for that study were people who were radar technicians and operators, people who were exposed to high powered sources.

Senator FORD. How did you estimate the nature of the subjects' exposure?

Major LARSEN. Well, sir, that gets a little fuzzy. The reason that it gets fuzzy is because, as you know, we do not have a usable personal dosimeter, so there is no way to measure what someone actually was exposed to in an occupational setting. What we have to do is break it into broad categories based on the power levels of radars that these people would be working on. For example, people working on air defense radars would be expected to be exposed to high-powered fields; whereas people working on tactical communications or guidance radars would be exposed to lower-powered fields. It is a qualitative, rough scale. It is not a precise scale at all, sir.

Senator FORD. How do you explain the different results from other studies?

Major LARSEN. Could you clarify the question, sir?

Senator FORD. Well, I guess you must be in disagreement with Dr. Milton Zaret?

Major LARSEN. I think the nature of the disagreement there is one of whether or not there is a microwave-specific cataract. It is my understanding from Dr. Appleton, who is the chief of ophthalmology at Walter Reed, that there is no such thing as a microwave-specific cataract. This is the major point of disagreement with Dr. Zaret.

So it is not a question of people having cataracts or not having cataracts. It is a question of what was the cause of the cataract; whether it was microwave irradiation; whether there was some kind of intercurrent disease, such as diabetes; whether there was a history of previous ocular trauma; whether there was hypertension, et cetera.

Senator FORD. Captain Tyler, you stated that in 1970 the Bureau of Medicine and Surgery determined "the need for medical and biological information about the effect of nonionizing electromagnetic irradiation was of sufficient importance to warrant extraordinary attention and emphasis." Upon what basis was such a determination made?

Captain TYLER. Reviewing the literature at that time and also one of the major emphases to change the management system at that time was at the direction of the Assistant Secretary of the Navy for R. & D., Dr. Frosch.

Senator FORD. Run that by me one more time.

Captain TYLER. Part of it was reviewing the information that was available at that time; second, the Assistant Secretary of the Navy for R. & D. was not happy as a result of some of the events with the Navy's management to that date; and he directed that they have a new management system for this program.

Senator FORD. What was he unhappy about?

Captain TYLER. Well, part of it was a report that went into him concerning one of the projects that was ongoing at that time.

Senator FORD. Do I have to ask another question? Are you going to—are you going to say it was classified information?

Captain TYLER. No. It is not classified.

Senator FORD. Start talking and I will start listening.

Captain TYLER. It was a project that was ongoing. The medical department at that time reviewed the project and determined that it was scientifically not worth continuing and did not renew the contract for the project. The principal investigator of the project loudly complained to many people that the Navy was turning off the project when he was finding things and reached the level of the Congress and the Secretary of the Navy. As a result, Dr. Frosch appointed a specific committee of outside experts to review this project in detail.

The project was reviewed and in the report that went to Dr. Frosch, it concurred that the project was not worth continuing. It was poor research. It also criticized the Navy for taking 2 years to find out that the research was of such poor quality. As a result, Dr. Frosch directed that a new management system be instituted for this program.

Senator FORD. You know I am going to ask you one more question, don't you?

Captain TYLER. Yes, sir.

Senator FORD. What is the name of the project or was the name of the project?

Captain TYLER. It was a monkey cataract study being conducted in Hawaii.

Senator FORD. Did it have a name? You name everything.

Captain TYLER. It was called Cataracts in Primates, Microwave Exposure of Primates for Cataract Production.

Senator FORD. Just how widely accessible is the Navy's two volume report on ELF bioeffects relative to the Project Seafarer?

Captain TYLER. One, the Navy has submitted it to the National Technical Information Service, NTIS. Anybody who would like to have these documents can write NTIS, and acquire them.

It was also given wide publicity to various Members of Congress, to other Federal agencies, and to the officials in the particular States that were involved in Project Seafarer.

Senator FORD. Do you know how many volumes were printed?

Captain TYLER. 1,000 copies, sir.

Senator FORD. In your prepared comments, you refer to, and I quote "Some rather adverse and subtle effects associated with particular types of extremely low frequency exposure."

What are some of the effects and what was the basis of your statement that such effects are not considered probable if Project Seafarer goes into operation?

Captain TYLER. One of them has been alteration in the calcium binding parameters on the membranes of the brain. This starts to take place at about 56 volts per meter. At 45, 60, and 76 hertz, the Seafarer field is .07 volts per meter. They have found no alterations in the calcium binding below about 56 volts per meter at Seafarer frequencies.

Another affect that has been shown is some modification of growth parameters of slime mold, which is a primitive single cell organism. Again this takes place at power levels 2 to 3 times the order of Project Seafarer; at the Seafarer levels, there are no changes in effects.

The one area we are still investigating is reported effects on bird migration. In talking to many of the experts in ornithology and bird migration, they even notice effects when migrating birds pass over large populated areas, particularly well-lighted areas.

We have noted from the Wisconsin test facility that as the field is being turned on or turned off, there appears to be some slight deviation in the birds' course by radar tracking. Again this really hasn't been confirmed yet. We are planning additional studies this fall. There does not seem to be any changes in the birds migrating patterns when the Seafarer field was on in the steady state.

Senator FORD. Can you elaborate on recent allegations there is a relationship between pancreatic cancer and chronic exposure to microwave? Is there a suspected correlation?

Captain TYLER. Right now the only information we have is the two people that were working a number of years ago at Quonset Naval Air Station in the rework facility. Two of these people have shown up with what has been diagnosed as pancreatic cancer. They claimed they were working with TACAN, which is a radar for guidance of aircraft.

This spring the Navy went out and surveyed TACAN repair sites. We found that there was almost zero microwave irradiation from the equipment under the test conditions that they used. We also checked for ionizing radiation. There was no ionizing radiation. We have found no other personnel associated with TACAN showing up with pancreatic cancer or other cancers. The investigation is still underway.

One interesting thing to note is that from the recently published data of the National Cancer Institute which surveyed the entire United States for incidence of cancer, that pancreatic cancer within the Northeast United States, particularly around Rhode Island, has the highest incidence in that geographic area of practically anywhere else in the United States for some unknown reason.

We think at the present time it may be due strictly to the geographic area of these personnel; we don't know why various types of cancer have different incidences in different parts of the country. That is still an unresolved question.

I think this may be it. We have found no other evidence of cancer from the TACAN operations. I think it is kind of an inexplainable incidence that these two people working at the same place at the same time showed up with cancer. As with many other disease states, anomalies do happen.

Senator FORD. Well, I am going to have to leave here shortly. In fact, I have been called to a vote.

I will submit some further questions to you gentlemen. I will ask that you expedite the answers as quickly as possible. I thank you for appearing today and for your patience with a nonmedical Senator.

Thank you.

We have one additional witness, Guenther Baumgart, president of the Association of Home Appliance Manufacturers.

STATEMENT OF GUENTHER BAUMGART, PRESIDENT, ASSOCIATION OF HOME APPLIANCE MANUFACTURERS; ACCOMPANIED BY THEODORE CROLIUS, GENERAL COUNSEL, AHAM; AND VERLE BLAHA, LITTON MICROWAVE COOKING PRODUCTS DIVISION OF LITTON INDUSTRIES

Mr. BAUMGART. This will be very brief.

Senator FORD. You may proceed.

Mr. BAUMGART. I am Guenther Baumgart, president of the Association of Home Appliance Manufacturers, which represents the majority of the American microwave oven manufacturers. Lists of our members are attached to the testimony.

With me are Verle Blaha of Litton Microwave Cooking Products Division of Litton Industries, who is a member of our Microwave Oven Engineering Commission, and AHAM's general counsel, Theodore Crolius.

Throughout the years, we have cooperated fully in the development of microwave standards, in international standards work, with Underwriters Laboratories; and since 1968, with the Bureau of Radiological Health.

The industry helped substantially in this work because these were the first standards prepared by the Bureau for devices involving nonionizing radiation.

The then new regulations for microwave ovens then went into effect in October of 1971. There have been three revisions of the original standard since that time, which have added stronger provisions for more elaborate interlocks, more foolproof closures, and safe use labels.

However, the permissible emission levels have not changed since they went into effect in 1971. It is the best judgment of experts in the field that they don't need change.

Earlier in these hearings Dr. John Osepchuk of Raytheon presented very detailed, factual evidence on microwave oven safety. We would like to underscore three very important points from his presentation.

First, despite allegations to the contrary, microwave ovens which conform with the BRH emission standard meet, or are well below, the Russian exposure standards. These U.S. standards are also more conservative than the Polish, Czech, or the recent International Electrotechnical Commission standards. The IEC standards were approved for publishing worldwide by 22 nations, including Russia and the United States.

The second key point we would like to emphasize is that the BRH standards are 10,000 times below levels known to produce harmful effects, according to the American Medical Association's Committee on Occupational Toxicology.

Our third, and perhaps most significant point, is that with millions of ovens in use there is not one single injury on record from microwave oven emissions. And many of these ovens have been in use since the 1950's, well before the Federal standards came into being.

There have been a few lawsuits alleging injury, such as the *Ryan/Mulhauser* case, but these allegations were proven to be unfounded.

The reason for being so emphatic on these three points is that there have been many charges and implications pointed toward microwave ovens. A case in point was the June 19 CBS television program, "60 Minutes," which gave a report on electronic pollution which made erroneous implications about microwave ovens.

In truth, the BRH and a responsible industry has for years accomplished what Congress intended in the first place—the design, production, distribution, and use of safe microwave ovens.

The present Federal regulations for microwave ovens were costly to develop, and they are costly to use. They were very carefully designed to provide confidence in the product, and experts from all over the world concur with the Bureau that they do. At least in this one case, the record should show that the job has been done, rather than to allow loose speculation and unfounded allegations to undermine the effectiveness of that good work.

Thank you for letting me present this message.

Senator FORD. Thank you very much. Let me ask two or three questions.

Do you believe that the current microwave oven emission standard was formulated from an adequate data base?

Mr. BAUMGART. I do. I would like to have Verle Blaha comment on it, because he is a better technician than I am.

Mr. BLAHA. Yes. Not only do I believe it was formulated on a very conservative basis on what the data was presented at the time, but I think the data continues to show that the standard is very conservative and accepted worldwide.

Senator FORD. Do you happen to know on what scientific basis the Bureau of Radiological Health arrived at the emission standards?

Mr. BLAHA. To my knowledge, they used all of the data available at the time the standards were set. This was in the 1969–70 period of time. The data was, as you heard from DOD this morning, OSHA—I forget the number of the committee, but the scientific committee that established the exposure standard for the United States.

Senator FORD. Did I understand Mr. Baumgart right; the standard has been changed three times?

Mr. BAUMGART. Yes. There have been three relatively minor but important modifications to the standard. They were to the administration of the standard. They were not on the level of radiation permitted. They were as I enumerated.

Mr. BLAHA. There were three changes made. One, it upgraded the standard to provide an additional interlock that monitors the other two; second, they clarified the standard relative to intrusion proofing; and third, there was the addition of a label required in the service handbook as well as on the face of the oven.

Senator FORD. Does that label information provide the customer a way to determine the amount of leakage from their ovens over a period of time?

Mr. BLAHA. No. The requirement is that the microwave oven must not leak for the entire lifetime greater than the emission standard.

Senator FORD. Do they ever?

Mr. BLAHA. I cannot think of a microwave oven that has leaked greater than the standard, providing it was not damaged in some way.

Senator FORD. Does the regulation require that you tell the consumer what to do in case the oven is damaged? For example, if the housewife hits it with a heavy cast iron skillet that we use to make cornbread out of or something of that nature?

Mr. BLAHA. I think you will find under any normal kitchen use, if you include hitting it with a cast iron skillet as being normal, that the microwave oven will still not leak in excess of standards.

However, the last change made was to include the label that said if the oven has been damaged, if the door is loose, then do not use and, instead, call a service agency.

Senator FORD. What are your compliance efforts?

Mr. BLAHA. Can you be more specific? You mean compliance efforts to substantiate the standard is met?

Senator FORD. Yes, sir.

Mr. BLAHA. It's a great deal of effort. One, every oven that is produced is monitored at least once on the production line to assure that it meets the standard.

Second, there is a continuous program of quality control. There is a continuous program monitoring the mechanical structure of the oven. The program involves a live test, a continuous door-slam operation, and the industry standard that has been cited for the lifetime of a door slam is 100,000 door slams. It's quite routine for microwave ovens to far exceed that requirement.

Senator FORD. You sent out this information with the ovens. Do you make any efforts to see that the consumer or customer complies with this information that you send along with the oven?

Mr. BLAHA. There has been a great deal of resurvey and surveying in the field, both by the BRH as well as the industry. Many thousands of ovens have been resurveyed after 1, 2, 5, and even 10 years of use. This survey gives us very good data showing that the microwave ovens are not exceeding the standard.

Mr. BAUMGART. There is also, Mr. Ford, a good deal of consumer education effort on the part of the industry as a whole and on the part of the manufacturers individually to have general articles in magazines and in newspapers—consumer columns, that sort of thing—appear to remind consumers about these things that Mr. Blaha has been describing.

Senator FORD. Has the Consumers Union modified its positions on the ovens?

Mr. BAUMGART. I know of no change.

Senator FORD. Still the same?

Mr. BAUMGART. I understand it is.

Mr. BLAHA. I know of no change.

Senator FORD. Has the industry undertaken statistical studies to determine health hazards associated with the use of microwave ovens?

Mr. BLAHA. As an association, we have continued to advocate future research. We cover this in two types of areas.

We have asked Dr. Michaelson to follow all research worldwide; evaluate it, give us an opinion as to the effects, results, status of this research.

Second, as an association, we have continued to encourage Dr. Guy, from the University of Washington, to continue his research.

Senator FORD. Is this an ongoing research that continues all the time?

Mr. BLAHA. Yes; this has been ongoing for several years.

Senator FORD. Since there is apparently so little known about the effects of microwave radiation, maybe this is a question you can't answer but one way: Do you think it's wise for people to expose themselves to it voluntarily?

Mr. BLAHA. If you are asking exposure to microwave ovens, the exposure is so absolutely miniscule—very, very small—that it's immeasurable, not measuarble. I state this because if you actually take an instrument and measure it for the person in the kitchen, where he is normally standing, you cannot measure the power density.

[The lists referred to follow:]

APPENDIX 1

MAJOR APPLIANCE MEMBERS

Absocold, Addison, Arvin, Blackstone, Boston Stove, Broan, Carrier, Design & Manufacturing, Ebco, Fedders; Airtemp, Norge, Fedders Refrigeration, Friedrich, General Electric, Major Appliance Business Group, General Motors, Frigidaire Division, Gerling Moore, Glenwood Range, Hardwick Stove, Hoover, In-Sink-Erator Division of Emerson Electric, Jenn-Air, KitchenAid-Hobart, Litton, Magic Chef, Gaffers & Sattler, Maytag, McGraw-Edison, Air Comfort, Modern Maid, Speed Queen, Intl. Metal Products, Natl. Union Electric Emerson Quiet-Kool, Preway, Revco, Rockwell International, Admiral, Roper, Tappan, Anaheim, O'Keefe & Merritt, Vernco, West Bend, Whirlpool, White Consolidated Industries; Athens Stove Works, Franklin-Freezer Division, Franklin-Laundry Division, Gibson Products Belding, Gibson Appliance, Greenville Products, Kelvinator GR Manufacturing, Kelvinator Appliance, Kelvinator Intl., Kelvinator Comm. Prods., White-Westinghouse White-Westinghouse Appl. Columbus Products, Mansfield Major Appliance, Edison Products.

PORTABLE APPLIANCE MEMBERS

Aluminum Specialty, American Electric, Arvin, Capitol Products, Clairol, Conair, Farberware, General Electric, Gillette, Hoover, Intermatic, KitchenAid-Hobart, Markel Electric, McGraw-Edison Port. Appl. & Tool, Time Products, Metal Ware, Mirro Aluminum, National Presto, Regal Ware, Richmond Cedar, Rival Titan, Salton, SCM Corporation Proctor-Silex, Scovill Dominion, Hamilton Beach, Son-Chief Black Angus, Sperry Remington, Sunbeam Oster, Superior Electric, Vita Mix, Waring, Wear-Ever, West Bend.

ASSOCIATE MEMBERS

AMP, Inc., Armco Steel, Bethlehem Steel, Calgon, Clorox, Colgate-Palmolive, Copeland, Corning Glass Works, Davis Walker, Drackett, Eagle-Picher Inc. Chi-Vit Corp., Eaton Corp. Auto. & Appliance, Control Operations, Economics, Lab., Electro-Therm, Emerson Electric; Browning Mfg., Chromalox, Emerson Motor, Fusite Division, Therm-O-Disc, Tuttle Electric, U.S. Elec. Motors, White-Rodgers, E. L. Wiegand; Ferro Corporation, General Electric, Gould, Inc., Hooker Chemicals, Inland Steel, International Nickel, Lever Brothers, Litton (Electron Tube), Mallory Timers, Monsanto, MSP Industries; Easy Heat-Wirekraft, Owens/Corning, Proctor & Gamble, Ranco, Raytheon, Robertshaw, Scott & Fetzer, Kingston Division, Kirby Company, Scott Paper; Foam Division, Singer; Control Division, A. O. Smith, Tecumseh, Teledyne. Texas Instruments, TRW Incorporated; United-Carr Division, Union Steel, U.S. Steel, Westinghouse Electric, White Consolidated Industries; Americold Compressor.

APPENDIX 2

MAJOR APPLIANCE PRODUCTS

Compactors, Dehumidifiers, Dishwashers, Disposers, Clothes Dryers, Food Freezers, Humidifiers, Microwave Ovens, Ranges, Refrigerators, Room Air Conditioners, Clothes Washers.

PORTABLE APPLIANCE PRODUCTS

Air Heaters, Blenders, Broilers, Can Openers, Clocks, Coffeemakers, Drip Coffeemakers, Coffee Mills, Coffee Maker Urns, Cookers—Egg, Cookers—Multi-Purpose, Corn Poppers, Curling Styling Wands, Fans, Fondues, Fry Pans (Skillets), Griddles, Hair Dryers, Hair Setters, Hamburger/Sand. Grills, Heating Pads, Hot Lather Machines, Hot Plates, Ice Cream Freezers, Ice Crushers, Irons (Dry), Irons (Steam & Spray), Juicers, Kettles, Knives, Lighted Mirrors, Manicure Sets, Massagers, Mixers (Portable), Mixers (Stand) Shavers, Slow Cookers, Steam Clothes Wands, Styling Combs, Timers, Toasters, Waffle Irons, Warming Trays.

Senator FORD. I am going to have to leave. There will be some questions that we will want to submit to you gentleman for answers. I hope that you will be able to, at your earliest convenience, answer them.

This hearing is recessed until 10 a.m. in the morning.

Thank you all.

[Whereupon, at 12:42 p.m., the hearing was adjourned, to reconvene at 10 a.m. on Tuesday, June 28, 1977.]

[The following information was subsequently received for the record:]

ASSOCIATION OF HOME APPLIANCE MANUFACTURERS,
Washington, D.C., September 15, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science and Transportation, Russell Senate Office Building, Washington, D.C.

DEAR SENATOR MAGNUSON: Following is submitted in response to the additional questions enclosed with your letter of August 15, 1977 and is further AHAM testimony to the Senate Committee on Commerce, Science and Transportation on its Oversight Hearings on Radiation, Health and Safety held on June 16–17, 27–29, 1977. The questions are answered in the order in which they are presented:

Question 1. Aside from encouraging research, has the industry undertaken any statistical studies to determine any potential health hazards associated with use of microwave ovens? If not, why not? Is it reasonable to expect the industry to be capable of self regulation?

Answer. Yes, the industry does conduct studies concerning the potential health hazards associated with exposure to microwave energy. These include continuing surveillance study and assessment of all published literature and attendance at all major meetings on the subject by Dr. Sol Michaelson, University of Rochester, AHAM's microwave bioeffect consultant.

These studies have shown conclusively that compliance with the BRH regulations for microwave ovens provides more than adequate protection against any potential health hazards. Individual manufacturers survey sample populations of their products and report all instances of non-conformance to BRH. The Bureau also conducts its own independent surveillance program. This overlapping surveillance will detect populations of products with as little as one percent out of compliance. With deliberately conservative regulatory requirements, the low threshold and sensitive surveillance provides adequate assurance against potential health hazards.

Question 2. Does the industry provide customers with a way to determine the leakage from their ovens after the time of purchase? How does one know whether the oven is meeting the standard after it has been purchased?

Answer. Yes, most manufacturers have leakage measurement instruments at their product service locations and will make measurements for a fee. This service is also available through public health service channels. If overt damage provides a clue that leakage might be higher than regulatory limits, then such measurements should be made. The user is warned to look for overt damage in the precautions section of the owner's manual and a warning label with the same message is usually applied to the product. Modern designs have very durable closure systems which will provide full protection in all but the most obviously damaged operating conditions. On the other hand, in order to detect the low energy levels involved with adequate accuracy, leakage instrumentation is relatively fragile and intricate. Thus, the preferred approach is to make professionally maintained instrumentation available through product service rather than on a "do-it-yourself" basis.

Question 3. What procedures are followed to assure that microwave oven salespeople are providing accurate information to prospective purchasers?

Answer. Manufacturers provide training and safety literature to retail salespeople so that they can provide accurate information to the prospective purchasers. Most manufacturers also train representatives to demonstrate the cooking ability of the ovens. These representatives are highly skilled in the proper use of the oven and are trained in its safety aspects.

In addition, the industry, both individually and collectively through AHAM, cooperates with the consumer press to have the safety considerations of microwave ovens presented properly.

In addition, all manufacturers have a special section in their use and care manuals which provides detailed safety information on the proper use of the microwave oven.

Question 4. How does AHAM explain the BRH's approval of the General Electric Company's plan to correct potential microwave leakage problems in 36,845 ovens?

Answer. Mr. Blaha, speaking from his personal experience in his reply to Senator Ford stated, "I cannot think of a microwave oven that has leaked greater than the standard, providing it was not damaged in some way." The General Electric microwave leakage problem involved the seal. Between a half and one percent of the 36,845 General Electric ovens involved leaked in excess of the regulatory level. The closure for these ovens was unique in the industry. The problem was traced to a manufacturing variance situation in which seal deterioration could take place in use on a small fraction of the production. An add-on seal system was developed to provide further assurance of closure integrity. It is being applied to all ovens of this class that can be found, whether their microwave leakage is abnormal or not. Mr. Sherwin Gardner, Acting Commissioner of the Food and Drug Administration, stated the following in the February, 1977 *FDA Consumer:*

"We are requiring this repair program because the door seals on these ovens can deteriorate with use, resulting in a leakage of microwave radiation above that permitted by FDA's strict safety standard. The repair program is designed to assure that the door seal will meet our safety standard for the entire life of the ovens.

"We see no danger from consumer use of the ovens during the time it will take to repair them under the precautionary program."

Question 5. Please provide the Committee with additional specific support for AHAM's opinion that the FDA–BRH Microwave Oven Performance Standard was formulated from an adequate data base.

Answer. There are four generally recognized classical studies on heating due to microwave exposure. These are:

(1) Cook, H. F.; "A Physical Investigation of the Heat Production in Human Tissues when Exposed to Microwaves"; *British Journal of Applied Physics;* Volume 3, Page 1, 1952.

(2) Herrick, J. F. and Drusen, F. H.; "Certain Physiologic and Pathologic Effects of Microwaves"; *Electrical Engineering;* Volume 72, Page 239, 1953.

(3) Schwan, H. G. and Li, K.; "The Mechanics of Absorption of Ultra-High Frequency Electromagnetic Energy in Tissues as Related to the Problems of Tolerance Dosage"; *IRE Transactions;* P.G.M.E., Volume 4, Page 45, 1956.

(4) Schwan, H. G. and Preisol, G. M.; "The Absorption of Electromagnetic Energy in Body Tissues—A Review and Critical Analysis"; *American Journal of Physical Medicine;* Volume 34, Page 425, 1955.

These documents form the basis for the recognized United States exposure standard.

The ANSI Standard C95.1, Safety Level of Electromagnetic Radiation with Respect to Personnel, was reaffirmed by the American National Standards Institute C95 Committee in 1974.

The BRH/FDA Microwave Oven Performance Standard was based on the ANSI C95.1 Standard. However, it employs an extensive safety factor to account for an uncontrolled population using the microwave oven and translates the standard into a product emission standard thus making it extremely conservative in terms of microwave exposure.

The above cited documents and all literature subsequently generated by them were extensively reviewed by the Tri-Services Program completed in 1965. The Tri-Services Program could determine no reason to change the exposure standard.

This information was again extensively reviewed in the May, 1968 hearings before the Senate Commerce Committee.

In specific consideration of the Microwave Oven Standard, all existing literature was extensively reviewed at the Symposium on the Biological Effects and Health Implications of Microwave Radiation sponsored by the Medical College of Virginia with the support of the BRH on September 17–19, 1969 in Richmond, Virginia.

In addition, a panel of the country's foremost radiation experts convened as a BRH Advisory Committee, called the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), further reviewed the literature and subsequently approved the BRH–FDA Microwave Oven Performance Standard.

Question 6. Please submit the report which you cited in your oral testimony—that of the American Medical Association's Committee on Occupational Toxicology.

Answer. Attached is a copy of the editorial on microwave ovens which appeared in the *Journal of the American Medical Association* March 8, 1971, Volume 215, #10, which was prepared by the AMA Committee on Occupational Toxicology.

Question 7. Since the hearings, two incidents of microwave ovens causing severe burns have been reported in Kentucky. Do the reports indicate non-compliance by the manufacturer?

Answer. No. The impounded products were found by BRH to be in conformance with the standards. Microwave burns are not possible under those conditions. A possible explanation is that the burns were nonmicrowave induced, resulting either from hot surfaces inside the oven or steam coming from the products being removed from the oven.

Question 8. In your testimony before the Committee, you stated that there had been no reports of injury caused by microwave ovens. Do the Kentucky incidents constitute the first reports of injuries caused by microwave ovens?

Answer. No, while the injuries are clearly associated with microwave ovens (as in the case of a head injury from collision with an open door cited in the Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) report) these burns have not been shown to be caused by microwaves. The matter is still under investigation by the manufacturer and by BRH, and AHAM is following the issue very closely.

Sincerely yours,

GUENTHER BAUMGART, *President.*

Attachment.

MICROWAVE OVENS

In the past two years there has been considerable interest and some confusion concerning the protection of microwave oven users from "radiation" hazards. The passage of the Radiation Control for Health and Safety Act of 1968 (PL 90–602, October 1968) has intensified the concern of the general public. It is unfortunate that many people confuse microwave radiation with ionizing radiation. Such misunderstanding has led to several unfounded press articles concerning injury from exposure to microwave ovens. The practicing physician may be confronted with such misinformation and questioned by his patients.

Microwaves, a form of radiant energy, are widely used in radar, communication relay systems, and various commercial and industrial applications. One characteristic of microwaves is their ability to bounce or deflect off metal surfaces, a characteristic basic to their use in radar. Another is their thermal or heating effect, utilized in microwave cooking. The molecular structure of a particular substance determines whether microwave energy of a given wavelength is transmitted, reflected, or absorbed. Microwave energy is transmitted by air and glass, reflected by metals, and absorbed by human tissue and foods. Only when the microwave energy is absorbed is there a heating effect. In foods, the increase in temperature is rapid and makes quick cooking possible.

Biological effects resulting from excessive exposure to certain microwave frequencies, are not completely understood. The effects of heating have been extensively studied. The body feels heat at a level far below that necessary to cause injury during short exposures. Some researchers have suggested that biological changes may be produced at much lower levels of microwave energy densities than those which cause heat effects.

Research studies with radar units utilizing microwaves from approximately 200 to 24,000 magahertz have shown that microwaves can produce injury in experimental animals. The biological effects and the degree of local damage produced by microwaves depend largely on the severity of exposure and the part of the body irradiated. The severity of exposure varies with the frequency or wavelength, power density, and duration of exposure and other factors. Near some radar antennae the power density is several orders of magniture greater than the allowable emission levels from microwave ovens.

Microwave exposure can cause skin burns and may affect the eyes and other organs. Exposure directed at the eyes of rabbits has resulted in various ocular effects, including cataracts, while direct exposure of the testes of rats has led to degenerative changes. Cataracts have been produced in some men engaged in the manufacture, servicing, or repair of microwave (radar) generating units. Alleged injury associated with radar radiation cannot be extrapolated to microwave oven exposures because the high-power densities and peak powers used in radar units are far greater than those developed in microwave ovens.

Since 1950, microwave ovens have been operated for perhaps 100 million hours without producing any reported injury to housewives, cooks, or other users. In spite of this record of safety, microwave radiation injury could occur if the manufacturers' instructions for operation, care, and servicing are not followed. This may happen (1) when those who use the ovens find ways to bypass the procedures or the mechanisms which are essential for their safe operation; (2) when the equipment, particularly the door or doors, become damaged; or (3) even when food particles are permitted to accumulate around the door seal, preventing the doors from closing tightly.

Microwave ovens manufactured to stringent safety standards, insure their safety under normal operating conditions. The standard adhered to by industry limits levels of typical exposure in normal use to approximately 1/10,000 the level known to cause harm to humans. Even under conditions of foreseeable misuse, safe margins are very likely maintained under this standard.

Accidental exposure is prevented by safety interlocks built into the ovens so that energy is shut off whenever doors are opened. Special door seals confine high levels inside the oven. Current industry standards call for the installation of at least two separate interlocks to insure fail-safe operation and special door construction limiting emissions to a low level.

The Secretary of the U.S. Department of Health, Education, and Welfare, through the Bureau of Radiological Health, has established an electronic-product program in accordance with the provisions of the Radiation Control for Health and Safety Act of 1968. The radiation performance standard for microwave ovens, developed under this program, requires that for ovens manufactured after Oct. 6, 1971, the leakage radiation shall not be above the limit of 1 milliwatt per square centimeter (mw/sq cm) prior to transfer to a purchaser. A limit of 5 mw/sq cm is applicable after acquisition by a purchaser.

Since it has been demonstrated that high-frequency stimuli may interfere with implanted pacemaker activity, patients with cardiac pacemakers should be warned that proximity to microwave radiation may alter pacemaker function. Reported studies have indicated changes in activity of some pacemakers when patients were within 5 feet of a microwave oven.

AMA COMMITTEE ON OCCUPATIONAL TOXICOLOGY.

RADIATION HEALTH AND SAFETY

TUESDAY, JUNE 28, 1977

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, D.C.

The subcommittees met at 10:02 a.m. in room 5110 of the Dirksen Senate Office Building, Hon. Adlai E. Stevenson presiding.

Senator STEVENSON. This morning we begin the fourth day in a 5-day series of hearings on radiation health and safety.

Yesterday's hearings dealt primarily with health effects of nonionizing microwave radiation.

Today, the emphasis will be on setting standards.

The National Institute for Occupational Safety and Health, the Occupational Safety and Health Administration, the Energy Research and Development Administration, the Nuclear Regulatory Commission, and the National Institute for Environmental Health Sciences all have responsibilities for assuring that citizens are not exposed to unsafe levels of ionizing and nonionizing radiation.

We will hear from representatives of all of these agencies this morning. We want to learn of their activities, whether those activities assure a safe environment.

Our first witness this morning is Lee Gossick, Executive Director for Operations of the U.S. Nuclear Regulatory Commission.

Mr. Gossick, do you have a statement? I would be happy to place it in the record.

STATEMENT OF LEE V. GOSSICK, EXECUTIVE DIRECTOR FOR OPERATIONS, U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, D.C.; ACCOMPANIED BY RICHARD CUNNINGHAM, ACTING DIRECTOR, DIVISION OF FUEL CYCLE AND MATERIAL SAFETY; ROGER MATTSON, DIRECTOR, DIVISION OF SITING, HEALTH AND SAFEGUARDS STANDARDS; AND HAROLD T. PETERSON, JR., SENIOR ENVIRONMENTAL PHYSICIST, OFFICE OF STANDARDS DEVELOPMENT

Mr. GOSSICK. I would like to use parts of the statement. I can abbreviate it to some extent.

Senator STEVENSON. Please proceed.

Mr. GOSSICK. Mr. Chairman, we are pleased to have this opportunity to speak with the committee on the subject of radiation protection. I understand that your primary interest is the adequacy of current research and regulatory efforts.

Essentially all of the activities of the Nuclear Regulatory Commission fall within that area of interest. The Commission is responsible for the licensing and regulation of nuclear materials and facilities, including nuclear powerplants, under the provisions of the Atomic Energy Act of 1954, as amended. We see to it that such facilities are properly located, designed, constructed, and operated to protect people against the hazards of radiation leakage or accidents. We also assure that people and the environment are protected from possible hazards arising from the storage, handling, and transportation of nuclear materials used in research reactors and laboratories, hospitals, and industry.

Because of NRC's relatively short history, many of our research programs and some of our regulatory programs are new and still developing. However, we have in place today definitive and proven effective programs for protecting workers and the public from exposures to radiation arising from the routine operation and anticipated incidents associated with the production of electricity by nuclear power.

The Energy Reorganization Act of 1974 provided for research "... which the Commission deems necessary for the performance of its licensing and related regulatory functions." Such supportive research is of a confirmatory nature as differentiated from development of reactor or safety system designs.

Despite the fact that radiation is probably the most studied of any potential occupational hazard or environmental impact, we continue to identify areas where the available scientific and engineering information is less than desirable for regulatory decisions. These gaps in knowledge generally can be filled by research or by the collection and analysis of operating data obtained over a period of time.

In licensing actions where gaps in knowledge are known to exist, we can make conservative assumptions pending the results of research. Thus, in the long run, once the results of confirmatory research are available, they generally permit better definition of a margin of safety and appropriate adjustment or removal of conservatism in subsequent licensing actions.

We have requested about $130 million for the NRC research program for fiscal year 1978. About 80 percent will go to reactor safety research, 12 percent to environmental and fuel cycle research, and 8 percent to safeguards research.

Essentially all of our reactor safety research program concerns the mechanical and physics aspects of reactor engineering. This research is supportive of technical areas in licensing reviews.

Some of the fuel cycle and environmental research program parallels the one for reactors, being oriented to the mechanical and physics aspects of nuclear fuel facilities, such as uranium milling, fuel fabrication, chemical processing, transportation and waste management. Other elements of this program particularly germane to this hearing involve analysis of the movement of radioactive materials in the environment, interaction of radiation with plants and animals, and effects of ionizing radiation on people—including potential health effects from occupational exposures and from environmental levels of radioactivity. This research program includes epidemiological studies of the effects of low-level radiation exposures. This work is relatively new for NRC and it closely tracks the larger, more broadly based and more basic research programs of the Energy Research and Development Administration and the National Cancer Institute.

The committee has asked whether we are aware of new or emerging technologies which are likely to produce new radiation hazards. We are not. However, there are a number of known radiation sources of potential concern which require more attention than previously afforded. Two examples of such sources of current concern to the NRC are naturally occurring radioactive materials and accelerator produced radioactive material, neither of which is currently subject to NRC regulations. In these areas, the objective should be to assure that all radiation exposure, whether it arises in medical, commercial, industrial, military, or power production activities is controlled with a uniformly applied, prudent public health policy derived from consistent application of the extensive base of scientific information on radiation effects.

Because of this concern and in response to requests by some States and by the Conference of Radiation Control Program Directors, the Commission directed a task force to study the matter of the need to regulate the use of naturally occurring materials and accelerator-produced materials and to present findings with respect to the adequacy of existing regulations. This task force has recently completed a draft report which is now being reviewed within NRC. The task force found that authority to regulate naturally occurring and accelerator-produced radioactive materials by State and Federal Governments is fragmented among many departments, commissions and agencies which overlap in some areas and leave gaps in others.

The task force recommended that the NRC seek legislative authority to regulate these materials because they present significant radiation exposure potential and because of the fragmentary and nonuniform controls now available. Reviews and formal views on this matter will likely be sought by the Commission from other Federal and State agencies as well as from the general public. The task force report should be available to the public within a few weeks.

The committee also asked about interagency cooperation. We find that there is a considerable degree of cooperation among Federal agencies, between Federal and State agencies, and on an international scale. This is particularly true where the expertise in a specific agency is useful and important to others in fulfilling their responsibilities which will have a substantial impact on the operation of others. The historic basis for this cooperation has two aspects: scientific and management. The scientific cooperation was fostered by the broad expertise and influence of scientific advisory bodies such as the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements. The management coordination was originated by the former Atomic Energy Commission in its approach to international and State programs. This policy emphasis has been continued by the NRC.

Elsewhere within the executive branch, the Office of Management and Budget and the Environmental Protection Agency have taken important management coordination roles in radiation protection matters in recent years. While there is considerable cooperation owing to these efforts, there is always room for improvement to produce more efficient regulation of commercial or research applications of radioactive material or radiation devices without decreasing protection of the health and safety of the public and radiation workers.

Among the areas where improvement is currently needed are (1) clearer definitions of limits of authority among agencies; (2) requirements for analysis of the net value of proposed regulations including the effects of their implementation; and (3) guidelines for judgments on the acceptability of risks.

We believe that some consolidation of Federal radiation activities would speak to these needs for improvement and could result in a reduction of duplication, particularly in the lines of authorities of EPA and NRC. Of course, any consideration of adjustments of authority within the Federal Government also could consider the important related issue of the alignment of authority between the Federal Government and the States.

For the present, there is some lack of balance in radiation protection and some costly duplication of efforts. The role played by EPA, within the current alinement of radiation protection responsibilities, is central to achieving needed improvements. For example, in the exercise of authority transferred from the now defunct Federal Radiation Council under Reorganization Plan No. 3, the EPA could assure uniformity and balance in radiation protection activities among Federal agencies. For example, this authority now assures that workers with medical X-ray machines and others working with cobalt irradiators are required to be protected to the same degree, even though responsibilities for regulation of the two types of devices reside in several places outside of EPA.

Similarly, EPA has authority to establish radiation standards for the general environment. In exercise of this authority it could also draw upon its expertise and authority in other areas to provide evenhanded treatment of a variety of industrial pollutants to assure an overall optimization and balance in expenditures to protect the environment. Or, as another example, EPA could assure that the limits on environmental effects of radioactive hospital effluents were given balanced treatment in light of the strict environmental limits now applied to the nuclear fuel cycle.

The NRC is supporting EPA's efforts in exercise of these two overriding, umbrellalike authorities for radiation standards. Such standards assure balanced requirements for control of environmental pollutants and hazards in the workplace.

We place particular emphasis on coordination in the development of EPA's environmental radiation standards. The inclusion of important NRC implementation concerns in EPA's recently issued regulation (40 CFR part 190) for the uranium fuel cycle is an example of interagency coordination to reduce its regulatory burden at no cost to environmental protection. Similar cooperation is needed and planned in connection with environmental radiation standards now being developed by EPA for radioactive waste management activities.

The committee has expressed a special interest in the protection provided for radiation workers. In the remainder of this statement I will concentrate on this area since it is of high priority to the Commission, and it illustrates the general philosophy and policy direction of the Commission in all radiation protection matters.

Several years ago, the Commission became aware of the generally rising trend of occupational radiation exposures at nuclear powerplants and took positive action to achieve more effective controls. We accomplished this through a system of regulation which requires that prescribed levels of protection be provided by licensees for their workers, and that unnecessary exposures below these limits be eliminated.

Prior to 1971, the practice was simply to require compliance with the radiation protection limits in our regulations. After several years of experience with this approach, it became evident that workers were receiving radiation exposures that were within the limits, but which, in some instances, could be further reduced with relative ease and at reasonable cost.

Exposure reductions appeared to be readily achievable through better facility and equipment designs, better worker training, and better operating procedures. Additional exposure reduction was considered desirable because of the Federal radiation protection policy to assume that some degree of risk is associated with any radiation exposure, however small. Therefore, in January 1971, title 10 of the Code of Federal Regulations, part 20, was amended to require licensees to assure that levels of exposure were not only within the limits but "as low as practicable." This approach is now well along in the implementation phase.

The first major step in implementing this approach was the issuance of a regulatory guide on occupational exposure control at nuclear powerplants. These facilities were chosen for this first effort because of the large number of workers employed and exposed in their operation, and the record of high occupational exposures, both individually and collectively, especially during maintenance operations. After this guide was issued, there were marked design and operational improvements. The guide has been recently expanded to better chronicle the favorable results and design approaches accomplished by industry design experts. I have a copy here which I would like to have entered in the record of this hearing.

Senator STEVENSON. It will be entered in the record.

Mr. GOSSICK. We are confident that this sort of guidance will lead to further exposure reductions across the full spectrum of facilities and activities regulated by NRC. For example, a similar guide will be issued for medical institutions within the next few weeks.

We are now placing additional emphasis on the concept of eliminating unnecessary occupational radiation exposures in all licensed activities, thus extending the experience we have gained in reactor applications. A plan of action was adopted by the Commission in February 1977, which will strengthen this aspect of our program across the full sweep of activities which we regulate. The major elements of this plan will require licensees (*a*) to develop written exposure control programs; (*b*) to meet minimum training requirements for workers, and special criteria for temporary workers; and (*c*) to employ radiation protection personnel of demonstrated competence in both the design and the operational phases of the nuclear facilities. Within NRC, the plan calls for independent study of methods to reduce exposures in licensed facilities and methods of reducing the amount of required maintenance on contaminated equipment.

Based on our considerable experience in controlling occupational exposures and on the recent successes of our initial implementation of these regulatory concepts with nuclear powerplants, we are confident that this program will succeed.

Mr. Chairman, we appreciate the opportunity to present the views and the program of the Nuclear Regulatory Commission in this important public health and safety area. We are prepared to respond to your questions.

I have with me Dr. Roger Mattson and Mr. Richard Cunningham.

Senator STEVENSON. Thank you, sir.

You mentioned the guidance for nuclear powerplants and medical institutions. In this guidance approach merely advisory? Is it mandatory?

Mr. GOSSICK. No, sir, it's required in the form of license conditions, required as a matter of being able to obtain the license in the first place.

These requirements are spelled out in the regulations which the licensee must meet.

The guide that I spoke of presents a way of meeting a certain requirement. It's not the only way. If the licensee can show an equivalent or better way of doing it, we will consider that and perhaps adopt it. The guide presents an acceptable way, so that if they follow it or reference it, it would meet our requirements.

Senator STEVENSON. How do you then enforce those requirements? I assume a licensee can satisfy your requirements. Then you must be concerned about their meeting these requirements in the operational phase?

Mr. GOSSICK. Yes, sir. We have a continuing program, Mr. Chairman, of inspection and enforcement. We have five regional offices throughout the United States that are charged with the inspection on a regular basis of all licensed activities, whether it be power reactors, hospital using radioactive——

Senator STEVENSON. Can you for the record give us a list of all the activities that require licensing? If it's difficult right now, we could have it later.

Mr. GOSSICK. I think that is in the written material we provided the committee earlier this week.[1]

Senator STEVENSON. You mentioned some sources that do not require licenses, that aren't controlled, natural sources of radiation and accelerator-produced radiation. In your opinion are there others that should be and aren't adequately controlled now?

Mr. GOSSICK. I think the majority of the ionizing sources of radiation are controlled now. The accelerator-produced isotopes are mainly for medicinal uses.

Senator STEVENSON. Would you elaborate upon your expression of "accelerator-produced"?

Mr. GOSSACK. Mr. Cunningham will respond to that.

Mr. CUNNINGHAM. Mr. Chairman, accelerators are machines that produce a high-energy particle which impacts on a material and creates a radioactive substance. The reason accelerators are becoming important is that they are a valuable tool in nuclear medicine. The next generation of isotopes that will be used in nuclear medicine will be largely accelerator produced. Currently, those isotopes used for most nuclear medicine diagnostic procedures are reactor produced. They are regulated by us. For the next generation, as nuclear medicine develops, more accelerator-produced isotopes will be used in hospitals. Accelerators will produce very short-lived isotopes, but at the same time it will take qualified radiochemists and physicists to manage these materials, get them in the proper form to put into patients. We will be seeing more of these as time goes no. They will not be subject under our current authority to our regulatory control.

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[1] See information submitted with matrices, *infra*.

Senator STEVENSON. "They," meaning the materials?

Mr. CUNNINGHAM. The materials themselves, sir, yes.

Senator STEVENSON. When you say "accelerator-produced" then, we are not talking about the accelerator. We are talking about isotopes produced by the accelerator and used principally in medicine.

Mr. CUNNINGHAM. Yes, Mr. Chairman, what we are addressing in the task force report are the radioisotopes themselves that must be taken from the accelerator, go through chemistry, put it into the proper form to put in the patient. The accelerators are ionizing radiation-producing machines in themselves.

The accelerators are ionizing producing machines themselves that we do not address in this task force report. Accelerators are among those, as are X-ray machines.

Senator STEVENSON. When will this task force report be ready?

Mr. GOSSICK. It's in the process of being reviewed within the Commission now, Mr. Chairman. It should be available within the next few weeks for public comment. We will be sending it to the other Federal and State agencies for their comments as well.

Senator STEVENSON. Natural sources of radiation. Are you suggesting that EPA or NRC or some other agency needs additional authority with which to regulate or control natural sources of radiation?

Mr. CUNNINGHAM. Yes, sir. The natural radiation we are talking about, from natural sources, is primarily from radium. NRC again does not have regulatory jurisdiction over radium. Radium has been used since the 1920's. It is still used in hospitals for some therapy and it is still used in industry for some purposes. Some States do regulate radium, but the control is uneven from jurisdiction to jurisdiction.

Senator STEVENSON. Is radium a natural source of radiation?

Mr. CUNNINGHAM. Yes, sir, it is. It is found in nature.

Senator STEVENSON. I understood that. Where is it found? In mines, quarries?

Mr. CUNNINGHAM. Yes, sir. Radium is one of the decay products of uranium. Uranium is a parent radioisotope. Associated with that, when uranium goes through a nuclear transformation, it gives off radiation, and one of the products down that decay chain is radium.

Radium is found with uranium. Before uranium became valuable, the ores bearing both uranium and radium were mined, and the radium separated and recovered for use. This is what Madame Curie did in the early days of the use of radium.

There is still a lot of radium around the country over which we don't have regulatory jurisdiction.

Senator STEVENSON. How seriously is radioactivity from natural sources?

Mr. CUNNINGHAM. We tried to determine that in the course of the NARM task force investigation. It's very difficult to do because the control is so fragmented. We know it is a problem, but the scope of the problem is not well defined because we don't have records on it and data have not been gathered as they are for other radioactivity subject to our regular programs.

The point is, though, that a lot of radium is being used around the country. It is found in the environment, and there are a number of potential problems we foresee associated with it. The exact dimensions of what this problem is are not well defined at this point.

Senator STEVENSON. You said, Mr. Gossick, NRC was studying the effects of ionizing radiation on humans. Could you go into more detail for us? Are you studying various levels of exposure, low levels?

Mr. GOSSICK. Yes, sir. This is a continuing program of the NRC. I would like to ask Dr. Mattson, who is knowledgeable in that area, to address that.

Dr. MATTSON. Mr. Chairman, the kind of research I think that you are referring to concerns the effects of radiation found in the environment, which would be very low levels, and the effects of radiation in the workplace, which would be somewhat higher levels, and how those effects are measured in human beings.

The body of information going back over about 50 years—back to Madame Curie in the early days—on the effects of radiation on man and animals is extensive. But as we come to lower and lower exposures, and as we come to different radioisotopes with which we are concerned, as Mr. Cunningham has expressed, we find there is need for continuing research to fill gaps in our information.

Another aspect of this is that the occurrence of health effects in large populations caused by very low-level carcinogens is very difficult to discern from the normal occurrence of ill health in those populations. Out of this has grown a science called epidemiology to study the occurrence of those statistical or low-level effects within large populations. It's the kind of research which spans many years of study and to which the National Cancer Institute, the Energy Research and Development Administration, and others have been turning in recent years. We more or less piggyback our confirmatory assessment needs on the research of those other agencies. We take small amounts of money and rather narrow interests and piggyback on larger research contracts to turn out results specially turned to our regulatory needs.

Senator STEVENSON. Did you hear or read Dr. Bross' testimony before this committee a week ago?

Dr. MATTSON. Dr. Bross?

Senator STEVENSON. Yes.

Dr. MATTSON. No. I did not know he testified here.

Senator STEVENSON. Are you familiar with his studies?

Dr. MATTSON. Yes.

Senator STEVENSON. Could you comment on his conclusions?

Dr. MATTSON. Dr. Bross has been engaged for some years in a study called the Tri-State study, an epidemiological study of the type I just described. About a year and a half ago he approached the Nuclear Regulatory Commission, my office in particular, to request our review or critique of that study. I believe it is performed under a contract from the National Cancer Institute.

Senator **Stevenson**. It was.

Dr. **Mattson**. The study was evaluated by the National Academy of Sciences in the course of the writing of the BEIR report in about 1970 to 1972, a report published in 1972. The BEIR Committee itself has been reactivated by the Environmental Protection Agency to look at that kind of information, especially new information which has become available since 1972.

I think EPA started that last summer, with the first report due this summer.

In addition to the new BEIR work which will include a report of Dr. Bross' study and others, we offered to meet with Dr. Bross in a public meeting conducted by our Office of Standards Development to review in a technical sense his Tri-State study, with peer appraisal, and to try to derive what we can from the study for our regulatory purposes.

It has been our opinion all along that current standards and current programs for controlling occupational exposure or environmental exposures to radiation properly account for Dr. Bross' work. He has consistently maintained that they do not and has asked for such a meeting. I believe it is due to be held this summer sometime.

Senator **Stevenson**. Well, it becomes very difficult for us laymen to know what to believe.

Mr. Gossick, perhaps that brings me to the Rasmussen report.

Recent reports concerning the manner in which the AEC conducted the Rasmussen Report on Nuclear Power Plant Safety raised doubts about the exercise of this responsibility by the NRC.

It has been charged and documents have been produced to support the charge, that the AEC exercised close editorial control over the Rasmussen report to insure that the report would not reach the conclusion raising doubts about reactor safety.

It has been further charged that the AEC did not submit the Rasmussen report to rigorous peer review procedures, that the AEC ignored many criticisms of the draft report that were submitted.

I have an article from Science, volume 197, entitled "Reactor Safety: Independence of Rasmussen Study Doubted," in which it says, "For instance, in a series of 1973 memos to Lavien, staffer Ed Gilbert wondered about what 'an objective reader of the report might think if the facts he discovered did not support our predetermined conclusions. Our RSS Report must find that the AE, the architect-engineer, the licensee, the vendors did an adequate job to ensure the safety and reliability of the two-plant study. What information do we need to gather to support such a finding? Disadvantages: The facts may not support our predetermined conclusions.' A later Gilbert memo said, 'The information we seek should serve to engender the readers' confidence about the AEC's role in insuring tight, quality workmanship which would not have the effect of raising unanswerable questions.' "

How do you respond to accusations like that?

Why should we have confidence in the research and regulation conducted by the NRC?

Mr. **Gossick**. Mr. Chairman, this is certainly a subject that has had a great deal of public attention. There have been critics certainly of the report and the report itself, of course, has been studied not only in this country but, for that matter, in some other countries. Some are just now undertaking studies of this kind which really was a first in using the method of analysis that the Rasmussen study did, of this very complex subject.

We have responded in a number of ways to the comments and the criticisms that have been raised. I think, contrary to any charge of suppressing staff views, this thing was about as openly addressed as anything that I have ever seen in the Federal Government.

There were documents which perhaps weren't identified or found in the public document room at the time that they were written, but almost everything that was produced as a part of this overall study was put in the public domain for everybody's scrutiny.

There were many, many comments of a critical nature, of all kinds of natures for that matter, received after the draft report was issued. Our own staff, as you have indicated from the Gilbert memo, commented extensively on the study. With regard to a predetermined conclusion, it may well appear in some people's honest views that there was a predetermination of the findings of the report.

Based on what I have seen—this study frankly was just getting started about the time I joined the AEC, and I am not an expert in this kind of methodology—I believe at least that all of the input brought into this study from outside the Agency and from many, many sources was taken into account.

In light of hearings held, other testimony given, other statements in recent weeks, there has been an effort by the NRC to assemble yet another independent group made up of critics, neutrals and proponents, if you will, of the nuclear power issue. It is going to be headed up by Prof. Hal Lewis from the University of California. All of the various issues that have been raised and the criticisms that have been levied will be addressed by this group.

The criticism, as I understand it, has been more addressed to the way in which the total study was summarized in the so-called executive summary—whether or not that summary of the study fairly and accurately represents the results of that study as reflected by the comments from the many different sources.

This study will be carried out during the summer months and a report issued, I would assume, by some time in the fall, Mr. Chairman.

Senator STEVENSON. What did you say about this fall?

Mr. GOSSICK. The report of this group that is now being formed will be, I think, available sometime in the fall.

Senator STEVENSON. And the report is specifically addressed to what?

Mr. GOSSICK. As to whether or not all of the criticisms and the various views have been accommodated in this report, whether or not valid conclusions were reached and summarized in the executive summary that was given wide publication—I think very, very few people read the full report. Most people read only the executive summary, which is a rather short document. The Commission is intent on seeing, as a result of this independent group consisting of proponents and opponents and people that are neutral perhaps, whether or not their conclusions are different to any significant degree from those reflected in the current summary report of the Rasmussen report.

Senator STEVENSON. So it is reviewing the adequacy of the Rasmussen report?

Mr. GOSSICK. Yes, sir.

Senator STEVENSON. And will the group review the procedure by which that Rasmussen report was produced, its integrity?

Mr. GOSSICK. They certainly will get into this. There is another important aspect this group has been asked to look at. That is how the application of, or the manner in which, this risk assessment methodology has been used can be further developed and applied in our licensing process.

Senator STEVENSON. Can you tell us who will be a part of this independent group?

Mr. GOSSICK. I don't have a list of the names with me, Mr. Chairman. I can certainly provide it for the record.

Senator STEVENSON. Would you please?

Mr. GOSSICK. Yes, sir.

[The following information was subsequently received for the record:]

WASH-1400 REVIEW GROUP

Dr. Harold Lewis, chairman (University of California).
Dr. Frank von Hippel (Princeton University).
Dr. William Rowe (Environmental Protection Agency).
Dr. Herert Kouts (Brookhaven Laboratories).
Dr. Walter Lowenstein (Electric Power Research Institute).
Mr. Robert Budnitz (Lawrence Berkeley Laboratories).
Dr. Fredrik Zachariasen (California Institute of Technology).

Senator STEVENSON. Professor Lewis, where is he from? How was he chosen to head this group?

Mr. GOSSICK. The University of California. He was chosen by the Commission after consultation with a number of people who had raised criticism of the report and whom we were solociting to serve on such a group. He is with the American Physical Society, as I understand it.

Senator STEVENSON. Is the NRC concerned about radioactivity from coal-fired generating plants? Who is going to have the responsibility for them?

Mr. GOSSICK. No, sir. Let me ask Dr. Mattson to touch on this subject.

Dr. MATTSON. The radiation that arises from the burning of coal, for example in thorium and uranium ores associated with coal, is not regulated. I know Dr. Rowe from EPA, when he testified here several weeks ago, spoke to the need to consider that source of radioactivity in the environment. Whether EPA adds radioactivity of that type to its emission controls for coal burning plants is yet to be seen.

Senator STEVENSON. Are you saying the EPA does not consider radioactivity emitted by coal-fired generating plants now?

Dr. MATTSON. No, sir. No one does.

Senator STEVENSON. What do we know about combustion, the burning of coal as a source of radioactivity? What is the state of the science?

Dr. MATTSON. We have measured, as I understand it, radioactive emissions from coal-fired plants and the increase in radioactivity in the environment of coal-fired plants. We know that burning of coal enhances ambient levels of radiation. We know that the levels are not high levels, but when you compare them to the levels of radioactivity which are required to be met for nuclear powerplants, they are not a lot different.

Senator STEVENSON. Not a lot different? Aren't they higher in many cases?

Dr. MATTSON. I couldn't speak to that.

Senator STEVENSON. Isn't the radioactivity emitted from unregulated coal generating plants higher than those emitted from nuclear fission generating plants? Do we not know?

Dr. MATTSON. Whether you can say that categorically for all the coal burning plants in the United States, I can't say.

Senator STEVENSON. I didn't mean all. It depends a lot on the kind of coal that is being burned?

Dr. MATTSON. Yes, sir.

Senator STEVENSON. No one controls the kind of coal that goes ito generating plants. Sulfur and other things, yes; but not for radioactivity; is that right?

Dr. MATTSON. That's right.

Senator STEVENSON. No State agencies either?

Dr. MATTSON. Not to my knowledge.

Senator STEVENSON. It raises some very large questions in my mind of going to coal without any perception of the consequences to the atmosphere. We have no solid data on the carbon dioxide emitted into the atmosphere from this process and its consequences, its effect on our environment, and the radioactivity associated with it. We are moving in this direction to get away from the radioactivity associated with nuclear fission. Of course, the electricity, as in the case of nuclear fission plants, has to be transmitted by high powerlines. We are becoming concerned about nonionizing radiation from those sources, which again we have no comprehension of.

Dr. MATTSON. Maybe we ought to address the point you just mentioned. We do consider the nonionizing radiation from high voltage transmission lines in the course of the environmental review that is done for nuclear powerplants. This is something which has only been done in recent times.

We have an excerpt from a recent environmental impact statement issued by the Nuclear Regulatory Commission considering the health effects and other effects of nonionizing radiation from transmission lines that we could submit for the record and your perusal.

Senator STEVENSON. Thank you.

[The following information was subsequently received for the record:]

5.6 OPERATION OF THE POWER TRANSMISSION SYSTEM

Aside from the esthetic impacts of transmission towers and lines from the Marble Hill Station (see Sec. 5.1), operation of these lines may cause the production of ozone. increased electrical fields, shock hazards. radio and TV interference, and acoustical noise. The use of herbicides during right-of-way maintenance also may be of concern.

Ozone and other gaseous pollutants, such as nitrogen oxides, are formed as a result of ionization of air molecules that surround the cylindrical conductors used for transmitting electrical energy at high voltages. This ionization is caused by electrical discharge that is termed corona. The degree of ionization depends on voltage, humidity, conductor diameter, surface roughness, and spacing between conductors. Calculations indicate that ozone production could be 45 times higher in foul than fair weather. Measurements at 345–kV lines show, however, that at ground level beneath the conductors the ozone concentration does not rise above ambient; furthermore, ground concentration of ozone is the same on foul days as fair days, presumably because factors favoring increased production rates also favor increased destruction rates.

Recently, experiments were run over a one-year period in Jefferson County, Indiana, on 765–kV lines running over open, flat cornfields. This is a situation closely duplicating much of the proposed Marble Hill 765–kV lines. When instruments were placed six meters downwind from the 765–kV conductors at conductor height where corona-produced ozone concentration should be greatest ". . . no ozone attributable to the transmission lines was detectable during the test." The natural increase in ozone concentration of two to three ppb for an increase of 30 meters in elevation was observed.

The sensitivity of measuring instruments is about ±2 ppb; hence, increases in ozone concentration above ambient due to corona from 765–kV lines are within the sensitivities of measuring instruments.

The national, primary, air-quality standard for photochemical oxidants prescribes a level of 80 ppb as a maximum one-hour arithmetic mean not to be exceeded more than once per year. Susceptible plant species show damage symptoms from ozone exposure at concentrations as low as 30 ppb, but over prolonged periods ozone is not considered injurious to vegetation, animals, or human beings unless concentrations exceed 50 ppb. On the basis of these considerations the staff concludes that ozone from Marble Hill Station's 765–kV lines will be environmentally inconsequential.

There is a possibility that electrical fields set up around transmission lines could affect persons in the field. Studies have been performed by members of the staff of the Johns Hopkins Hospital to determine whether exposure to electrostatic fields such as those existing in transmission line substations result in adverse effects on humans, and were reportedly by Kouwenhaven et al. The Kouwenhaven study gives the results of physical and medical examinations of eleven linemen over a period of 42 months during the time they were performing live-line maintenance work on a 345–kV transmission system. Measurements of currents induced in a man's body when doing typical work on a 345–kV system such as on transmission towers and in buckets were reported on. In the former case, the man is grounded while in the electric field and in the latter, he is at line potential (barehand work). Body currents of 100 to 400 microamperes for the tower work and from 85 to 840 microamperes for barehand work were measured, depending on degree of bucket shielding used. Field intensities also were determined at various parts of the bodies of men doing barehand work. These ranged from 0.4 kV/in (20 kV/m) to 12 kV/in (470 kV/m) at the top of the head to 0 to 4 kV/in (200 kV/m) at the knees, depending on whether full or partial bucket shields were used.

As a result of this study, the authors reported that

"Considering the period of observation (3½ years) and the method of study, it can be reported that the health of the eleven observed linemen was unchanged by their exposure to HV lines. Also no evidence of malignancy was found. There was a decrease in the sperm count of two of the 11 subjects. The significance of this is not clear and warrants further study; but no correlation has been found between exposure to HV lines and any effect on the health of individuals in this investigation. Among the 11 men tested, there were four who had had many hours of barehand work during the period of this investigation. Not a single one of these men showed any change in his physical, mental, or emotional characteristics. Their laboratory studies remained entirely normal. No evidence was found that an adequately shielded lineman is endangered in any way by working barehanded in a HV ac electric field, within the limits of this study."

Studies of this nature were also carried on in Russia and their results were reported at the 1972 International Conference on Large High Tension Electric Systems, Paris, France, in a paper by Korobkova et al. In this study, a systematic medical examination of about 250 persons working in 500–kV substations for a long time was undertaken. Measurements were also made of field strengths in various areas where these persons worked in 500–kV substations and similar locations in 750–kV substations. Field potentials up to 26 kV/m were indicated in the 500–kV substations.

The Korobkova report stated that "the examination showed that long-time work at 500-kV substations without protective measures results in shattering the dynamic state of the central nervous system, heart and blood-vessel system and in changing blood structure. Young men complained of reduced sexual potention." It was also concluded that "the depth of these functional diseases or troubles directly depends on the time of stay in the field." Criteria for permissible duration of personnel stay in electric fields were given and ranged from five minutes per day at 25 kV/m to unlimited time at 5 kV/m.

In a follow-on report by the Johns Hopkins staff members, results were given for the continued examination of ten of the previously examined linemen who were still employed by the power companies. The report covers a period of nine years ending June 1973 during which the men were examined completely seven times. There were no significant changes of any kind found in the physical examinations, neither were there any significant abnormalities in any of the laboratory studies. No disease states were found that could be in any way related to the exposure of the men to high-voltage lines.

The investigators were aware of the Russian paper and specifically looked for disorders described in it. In particular, no disorders in the functional states of the nervous and cardiovascular systems of the workers as reported by the Russians were found. The report cautioned, however, that in view of the two diverse populations examined, with entirely different cultures, working conditions and environments, comparison of the two different studies should be "viewed with great caution". The report of the follow-on examinations, therefore, did not change the conclusions reached in the earlier study.

A recent Russian paper, discussed during a US/USSR symposium on high voltage transmission, reiterated that extra high voltage (EHV) substation workers had experienced problems. In this discussion the Russians state, "If the exposure is of brief duration, the effect disappears. If the exposure is on an extended daily basis, the effects appear to be cumulative but ill effects disappeared in one month after removal from exposure." A second Russian paper stressed that present standards apply only to maintenance personnel working on electrical installations. Standards permitting higher voltage gradients for local populations and agricultural workers are currently being considered since these populations will be exposed only infrequently.

These studies did not incorporate controls and are limited in both scope and time. For example, cases are known where adults are unaffected by doses of agents that are teratological or lethal to the fetus or child, and lag times between dose and effect of 20 years or more are known. Since the above studies do not consider children, since children may play beneath the transmission lines, and since controlled studies of long duration have not been carried out, the long-term effect of high voltage transmission lines is currently unknown. However, the staff is not aware of any reported observable effects resulting from exposure to electric fields radiated from high voltage power lines. The physiological effects reported by the Russians were observed on workers in EHV substations, not on individuals below transmission lines.

The applicant's original application did not specify the exact design of the transmission system. But the staff knows that 765-kV systems are being built with the intention that the gradient within the right-of-way at a point of minimum conductor-to-ground clearance is 8 kV/m and at the edge of the right-of-way is 1.8 kV/m. If these gradients were to occur, using the more conservative Russian study, a man could daily spend three hours working beneath the lines with no adverse effects. The general public is not expected to spend significant amounts of time in the transmission line right-of-way corridors.

The applicant has specified in the letter of 30 April 1976 to the NRC that the maximum electrical field gradients at the point of minimum ground clearance will be designed to be 12 kV/m which is below the normal perception level. This will result in a field of 2.4 kV/m at the edge of the right-of-way.

The brief summation of the literature given above includes observations of adverse health effects on switchyard workers, but no such observations were reported from studies on transmission line worker and on individual outside the switchyard environment exposed to voltage gradients well above 12 kV/m. In the absence of such observations the staff does not believe that there should be changes in the applicant's proposed design. A number of carefully designed studies of the biological effects of electric fields are currently underway and additional studies are planned. The effects of transmission line voltage gradients on the general population will be studied, along with long-term effects. The staff will keep abreast of these studies and of any guidelines resulting from them, and will reconsider the impacts of the transmission line operation prior to or at the time of the Operating License stage review, taking into consideration any new information.

The applicant will minimize induced ground currents by grounding towers, fences, and rail lines where the transmission lines might interfere with railroad communication or signalling devices. Ground resistance tests will be performed for each tower. If the resistance to ground exceeds 10 ohms, the applicant proposes to install additional grounding to keep the value at 10 ohms or less under normal atmospheric conditions (ER, Section 3.9.5).

Induced currents are unlikely to ignite fuel vapors, but currents capable of shocking people could be induced in vehicles without grounding straps. Any stationary structure with metal parts in the right-of-way should be grounded by the applicant, especially such objects as metal fences or rail lines that run parallel to the right-of-way. In such objects that are ungrounded, shock causing involuntary muscle reaction may occur, but no permanent physiological harm is likely. The applicant is committed to ground such fences at intervals of 500 feet (150 m) within the easement strip (ER, Sec. 3.9.5). The staff believes these grounding measures will reduce the likelihood of shock to a level which is of no concern.

A transmission line design guideline pertaining to induced currents which the applicant plans to follow, and which the staff considers prudent, is that ground clearances should be maintained so that a maximum induced current of 5 milliamperes (rms) is not exceeded under conditions of maximum line sag when the largest anticipated truck, vehicle or equipment under the line is short-circuited to ground. This guideline will effectively reduce the applicant's specified maximum voltage gradient where large vehicles and equipment pass under the lines.

A four-conductor bundle of unspecified configuration, which the applicant intends to use (ER, Sec. 3.9.4), will minimize radio and TV interference from the line and give acceptable fair-weather reception beyond 200 feet (60 m) from the line. AM radio and TV reception will be degraded in any case if the receiving equipment is within 80 feet (25 m) of the right-of-way during foul weather, but there will be no interference with FM reception.

The applicant claims that no complaints about audible noise at the right-of-way edge of operating 765–kV lines have been registered (ER, Sec. 3.9.4). It has been stated that in fair weather audible noise produced at the edge of the right-of-way of a 765–kV line will be 37 dBA, which is too low to be heard. During a heavy rain the noise level can go up to 56 dBA, which can be heard, but the noise of the rain will likely override it. In any case, because the average office or home noise exposure is 75 dBA, the power-line noise would, at most, be a mild irritant. The applicant plans to use herbicides in the maintenance of the transmission line rights-of-way. For the staff's discussion of the terrestrial impacts of herbicide usage see Sec. 4.3.1.

In forested areas, removal of trees and shrubs along the transmission-line route will create edge habitats that may lead to an increase of animal and plant diversity in the area, whereas those species requiring unbroken forest in which to live will probably be subject to stress.

Impacts on aquatic ecosystems due to operation of the transmission lines will essentially be the same as described in Section 4.3.2, except that the use of herbicides to control the vegetation in the corridors must be considered. Aerial application of these herbicides could result in their entering the streams via runoff. In order to adequately protect the aquatic biota, the applicant shall be required to adhere to conditions set forth in Section 4.5.2.

5.7 URANIUM FUEL CYCLE

The environmental effects of uranium mining and milling, the production of uranium hexaflouride, isotopic enrichment, fuel fabrication, reprocessing of irradiated fuel, transportation of radioactive materials, and management of low- and high-level wastes are within the scope of an AEC (now NRC) report. Table 5.18 summarizes the contributions of such environmental effects.

The NRC Staff may subsequently modify or expand the discussion of environmental effects of the fuel cycle in the light of the Court of Appeals decision in *Natural Resources Defense Council* v. *NRC* (CADC Nos. 74–1385 and 74–1586 decided July 21, 1976). That decision is now being analyzed by the Staff.

5.8 IMPACTS ON THE COMMUNITY

5.8.1 Physical impacts

Because of the remoteness of the station, operational noise should affect very few persons. Moreover, noise emissions that do occur will conform to local, state, and federal guidelines and regulations (ER, p. 8.2–7).

Under certain meterological conditions, the plumes from cooling towers could increase ground-level fog. The frequency and extent of this physical impact, as well as the information concerning visibility of the plumes, are more fully discussed in Section 5–3–1.

As the plant construction reaches completion, traffic congestion is expected to be considerably less than during the construction peak. The upgrading of roads for the construction phase should be adequate for the operational phase.

5.8.2 Social and Economic Effects

5.8.2.1 Employment

The applicant has estimated that 544 people would relocate to the area within 10 miles of the Marble Hill station as a result of plant operation and maintenance. Within this group are 155 plant employees, 106 induced non-manufacturing employees, 123 school children and 160 other adults (ER, p. 8.1–5). Induced employees are those required to provide services to immigrating employees. After reviewing the available data, the staff concludes that the applicant's estimate of induced employees relocating to the area has been overstated. An important consideration in arriving at this conclusion is the high local unemployment rate. Some of the locally unemployed and underemployed would benefit from the direct and induced labor demands of the station during both the construction and operation phases.

5.8.2.2 Direct payroll and purchases

The applicant estimates that over the operating life of the Marble Hill facility, labor expenditures will amount to more than $216 million (1983 present worth). The applicant also estimates that 90 percent of the operating payroll will be spent within the region (ER, p. 8.1–6).

Senator STEVENSON. What can you tell us about those conclusions now?

Dr. MATTSON. There have been occasions when, upon review of the possible health effects or environmental effects of nonionizing radiation from transmission lines, the NRC staff has asked for the transmission line to be constructed or located in such a way as to reduce those environmental impacts. As to whether the potential effects are a significant health hazard in a particular location or not, all I can say is that if they were, we couldn't license that plant and still meet National Environmental Policy Act.

Senator STEVENSON. Can you tell?

Dr. MATTSON. Pardon me?

Senator STEVENSON. What are the health effects of these high powered transmission lines?

Dr. MATTSON. Health effects associated with nonionizing radiation.

Senator STEVENSON. Are they cumulative?

Dr. MATTSON. Mr. Cunningham, can you speak to that?

Senator STEVENSON. What are they?

Mr. CUNNINGHAM. I don't have any detailed knowledge.

Senator STEVENSON. Does anybody?

Mr. CUNNINGHAM. I don't have the detailed knowledge on the biological effects.

We have Mr. Hal Peterson in the back of the room. I think maybe he can speak to that.

Mr. PETERSON. Mr. Chairman, the effects of nonionizing radiation from high voltage lines lie in several areas. One is the neurophysiological effect that has been reported for RF fields, radio frequency fields. A second effect is the production of toxic gases such as ozone. A third is the induction of electrical shock from metal structures that are in the high voltage field from power lines. Another effect could be potential fire hazards due to spark discharges. Of these effects that are examined in the impact statement, the analysis shows that the apparent neurophysiological effects cannot be confirmed at very low levels.

A recent report by the Electric Power Research Institute has summarized the effects of electric fields. This is one of the best summaries, we feel, of those effects. It was prepared by the Illinois Institute of Technology for EPRI and is entitled, "Biological Effects of High Voltage Electric Fields," dated November 1975 (EPRI 381-1).

The primary effect in terms of health, is the buildup of static electricity on metal structures. To prevent this, we recommend to the licensee that metal structures in the area of the high-voltage transmission lines be grounded. Those are essentially the types of effects we look at.

Senator STEVENSON. Well, the same effects at the site of a generating plant could be experienced at any point along those transmission lines, could it not?

Mr. PETERSON. From the transmission line? Yes, sir. It has to do with the high-voltage field of the lines.

Senator STEVENSON. You are concerned about the effects at the site?

Mr. PETERSON. No, sir, not just the site. We take a look, as part of the impact statement review, at the entire transmission corridor up to the interconnection with the existing transmission system. In other words, we look at the portion that is unique to the nuclear plant itself. From there on in, to the user, the powerlines would not depend upon where the plant was or what type of plant it was. So up to the interconnection point is the transmission corridor we look at in the impact statements.

Senator STEVENSON. I see. You said the effects, the neurophysiological effects at low levels, can't be confirmed. I am a layman; I am having trouble. What are the low levels and what are the high levels? What are the levels we have to be concerned with in connection with these transmission lines? Are they so low as not to cause any serious concern? Or are they high enough to be concerned about?

Mr. PETERSON. Mr. Chairman, I am not totally familiar with the background of these effects. I do know that we have the same kind of uncertainty with these nonionizing fields that we have at the very low level effects of ionizing radiation. Different studies have shown different effects. The effects, to my knowledge, are generally in the nervous system. They are not genetic; they are not cancer; they are in the nervous reaction, how well animals can run through mazes, and so forth. There is some conflicting evidence.

I think we could prepare a summary of such studies.

Senator STEVENSON. How high do those levels have to get to be concerned about those effects?

Mr. PETERSON. Again, this Electric Power Research Institute study showed that field strengths of about 20 kilovolts per meter gave no indication of hazardous effects.

Senator STEVENSON. This is a study by the Electric Power Institute?

Mr. PETERSON. Yes, sir. This is a summary of all the studies performed. It is a literature review, as I understand it.

Senator STEVENSON. You are not relying on the Electrical Power Institute?

Mr. PETERSON. Not solely. We quote it because it is a thorough summary.

Senator STEVENSON. You are doing your own summarizing, I trust, too?

Mr. PETERSON. I think my best indication there, Mr. Chairman, is to say we will give the committee a summary of what is known about the health effects from transmission lines.

Senator STEVENSON. That would be very helpful to us.

[The following information was subsequently received for the record:]

UNITED STATES OF AMERICA, NUCLEAR REGULATORY COMMISSION, BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

(Docket Nos. STN 50-546, 50-547)

IN THE MATTER OF PUBLIC SERVICE COMPANY OF INDIANA, INC., ET AL. (MARBLE HILL NUCLEAR GENERATING STATION, UNIT NOS. 1 AND 2)

NRC STAFF SUPPLEMENTAL—TESTIMONY OF GERALD E. GEARS ON CONTENTION NO. 8

In this proceeding, the intervenors have advanced the following contentions:

SMH/STV.—The environmental impact of the 756,000 volt transmission lines has not been adequately evaluated.

Joint intervenors.—Inadequate evaluation has been given to the environmental effects of the 765 kV transmission lines to people, animals, and flora in the cost/benefit balance.

The Staff has considered the effects of electrostatic field's gradients on humans in the Marble Hill Final Environmental Statement (FES) (Section 5.6). The purpose of this testimony is to supplement the FES as related to humans, plants and animals. The Staff has pointed out in the FES that electrostatic field gradients from transmission lines have not been shown to cause medical ill effects on human populations. The Staff is working with EPA, ERDA, FEA, and other Federal agencies as a member of the Federal Interagency Advisory Committee on Electric Field Effects which is funding research on all aspects of electric field effects. Based upon the review of the latest findings on this matter, the Staff indicated that it does not believe that changes in the applicant's proposed design are warranted (FES, Section 5.6). The Staff further indicated that these impacts will be reconsidered prior to or at the time of the operating license (O.L.) stage review, taking into consideration any new information gained by the Staff.

To authorize construction of PSI's proposed 765 kV facilities, final decisions concerning acceptable levels of exposure to various effects, and consequent design or operating conditions, may be made at the O.L. stage except in one subject area—induced current shocks. Because the only practical ways now to ameliorate shock effects are to increase conductor-to-ground clearances or lower the voltage of the facilities, the Atomic Safety and Licensing Board (the Board) would have to decide now whether PSI's proposed line may be built and operated at 765 kV and would also have to determine proper clearances. It is our position that there is sufficient data on this subject that will permit the Board to make the necessary final determinations.

In another subject area—that of long-term electric magnetic field effects—the Staff realizes that there are uncertainties in this area. The pertinent point for the present is that possible protective measures do not include changes in tower design or conductor size or configuration. It is our position that 765 kV may be approved as the design voltage with reconsideration of impact data at the O.L. stage including possible imposition of protective conditions on 765 kV operation.

We will now address in greater detail the analysis which led to our position expressed in the FES. We will limit this expanded discussion to the areas of induced current shocks and biological effects of electric and magnetic fields.

I. Induced current shocks

The proposed 765 kV transmission line will induce an electric charge and proportional voltage on insulated conducting objects on or near the R/W. A person grounded through bare feet, shoes, or a grounded conducting object who touches such an insulated charged object may receive a current flow and experience "shock" effects of two general kinds—steady state (or "short circuit") current and transient current (or "spark discharge").[1] [2] The level of the induced charge will vary with a host of factors, including: Voltage (which affects electric field strength) ; transmission line conductor-to-ground clearance (which is affected by line loading and ambient temperature—the lower the clearance, the greater the charge) ; size of the insulated conducting object (the larger the object, the greater the charge) ; degree of insulation of the conducting object; and spatial relationship of the insulated conducting object to the transmission line conductors. The levels of steady state or transient currents experienced will also be affected by the degree to which the person touching the insulated object is effectively grounded.[3]

For steady state currents, direct physical harm occurs only above the "let-go" level—where involuntary muscle contraction makes the person unable to release the conducting object. The minimum "let-go" level for men is about 9 milliamperes (mA) and that for women about 6 mA. Based on this data, 5mA is being considered as the maximum "let-go" current in the proposed revision of Part 2 of the National Electrical Safety Code. At some point above the let-go level, respiratory arrest and consequent suffocation may occur if the current flows through certain parts of the body for a sufficient time. Below the let-go level but above the threshold of perception, steady state current flow may cause anything from mild surprise to a sudden, involuntary "startle" reaction of part or all of the body. While about 1 percent of children and small adults can perceive steady state currents of about 0.1 mA, the threshold of perception for 50 percent of the population is 1.0 mA.[4] [5] For transient currents, spark discharges at the maximum levels predicted for the proposed 765 kV transmission line will not cause any direct permanent physical harm, but may cause pain which might result in a sudden involuntary reaction.[6]

To protect people not only against direct permanent physical harm but also against possible indirect or secondary injury that might occur from an involuntary reaction to a shock current—such as from jerking a hand back and catching it in moving machine parts, a program of grounding—or grounding and bonding[7] of stationary, fixed conducting objects on or near the R/W (like metal buildings, roofs, or fences), without any change in voltage or facility design will be initiated by the applicant. Vehicles which may use or cross the R/W, however, present a more difficult problem, since they may not be equipped with grounding straps or chains. The largest vehicles which might park beneath the transmission line must be predicted and the shock currents people might experience from touching them determined.

A General Electric research project has tested various sized vehicles which might cross beneath 765 kV lines or travel the R/W, measuring actual steady state and transient currents from them under either a 345 kV line or the project

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[1] United States Department of Interior. Electrical Effects of Transmission Lines, Bonneville Power Administration, Sept. 15, 1975.

[2] United States Department of Agriculture. Electrostatic and Electromagnetic Effects of Overhead Transmission Lines, Rural Electrification Administration, May 1976.

[3] T. D. Bracken. 1976. Field Measurements and Calculations of Electrostatic Effects of Overhead Transmission Lines, IEEE Trans on Power Apparatus and Systems, Vol. PAS–95(2) : 494–504.

[4] C. F. Dalziel and W. R. Lee. 1969, Lethal Electric Currents, IEEE Spectrum, February, pp. 44–50.

[5] J. C. Keesey and F. S. Letcher. 1970. Human Thresholds of Electric Shock at Power Transmission Frequencies, Arch. Environ. Health. Vol. 21 : 547–552.

[6] Spark discharges from the proposed 765 kV line could conceivably—under "ideal" conditions—cause gasoline ignition if a well-insulated vehicle were being refueled from a grounded pouring spout underneath the line, but the probability is extremely remote. The only measure that has been recommended to guard against even this remote probability is an educational program to warn people not to refuel vehicles under the line.

[7] The Staff has also investigated recommendations for an educational program as part of the grounding and bonding program. The Staff is not convinced that such a program is now presently warranted.

UHV test line, for two sets of conditions.[8] [9] The first set of conditions used for these measurements and calculations—the "worst possible case"—were designed to demonstrate the maximum shock currents possible from the various vehicles. Under these contrived "worst case conditions" the vehicles were placed parallel to the conductors, in the location of lowest conductor-to-ground clearance, with the vehicles artificially insulated (for tests in a recently harvested alfalfa field, rubber mats were used to increase insulation). To assure effective electrical grounding in measuring the currents, copper ground rods were added. The second set of conditions—the "worst probable case"—representing more realistic conditions, eliminated ground rods and artificial insulation. From those measured values, steady state and transient currents that a 765 kV line would induce were calculated for the vehicles, giving levels for varying conductor heights and lateral distances of the vehicles from the transmission line's centerline.

The worst possible case steady state currents calculated as a result of these measurements are those for a person touching a large tractor-trailer truck. Where the minimum conductor-to-ground clearance is 48 feet, the worst possible case steady state current from the tractor-trailer would be 6.0 mA. With all other large vehicles that might pass under the lines or along the R/W—including a tractor-milk tanker, a school bus, a crop wagon and farm tractor combination, a Pitman "Skyworker" bucket truck, and a John Deere combine—worst possible case state current levels would be below the let-go level for children. Probable case steady state currents, on the other hand, would be only 4 to 12 percent of worst-case values, and therefore all would be well below a 1.0 mA level for minimum clearances ranging from 42 to 50 feet. The Staff recommends that the design of conductor-to-ground clearances provide a worst probable case steady state current limit no greater than 5.0 mA, the estimated let-go level for children, to protect them from the threat of direct permanent physical injury (FES, Section 5.6). The applicant has informally indicated to the Staff that proposed clearances will not exceed a maximum induced current of 5.0 mA (rms), based on its consultant's recommendation, when the largest anticipated truck, vehicle, or equipment under the line were short-circuited to ground. This determination shall be based on a final unloaded conductor sag at 120° F. The Staff requires this design criteria as a condition of any authorization to construct the facility to assure the accuracy of our assessment, which incorporates this design criteria. A 1.0 mA level to protect against possible indirect injuries caused by involuntary reactor to shocks has been recommended by some experts.

Admittedly, people can experience steady state shocks which will approach worst-case values, but those instances should be very rare. Even probable case conditions assume the unlikely concurrence of many factors: that a large vehicle be parked along the lowest portion of the conductor catenary, parallel to the conductors, at a time of maximum line loading and high ambient temperature. Worst possible case conditions assume additionally that the vehicle be well insulated and the person be well grounded, a situation generally precluded by field conditions, because the vehicle and the person would normally be standing on similar surfaces. Moreover, for an indirect injury to occur an additional set of conditions must coincide (which the Staff believes quite improbable): the large vehicle itself, or machinery very near it, must have moving parts in which a hand or clothing might be caught; the moving parts must be in motion when the shock is received; parts of the person's body or clothing must be near the moving parts; and the person would probably have to reach over the moving parts, without touching any other part of the vehicle until the hand is in the proper position where recoil from the shock would cause the hand or clothing to contact the moving parts. Consequently, the probability of indirect or secondary injury from shocks occurring is obviously well below even the probability that shocks above the 1.0 mA level will happen. In fact, the Staff knows of no reports of an indirect injury by EHV transmission line induced shock currents.

The Staff believes there is no evidence to warrant rejection of the proposed 765 kV facilities, merely to protect against the possibility of improbable indirect injuries caused by shock currents. It is practical to design the 765 kV line for 5.0 mA worst probable case steady state limit and the applicant has indicated that this will be done. If additional data from research and other sources determine the necessity of additional protection against indirect injury, operating conditions providing some type of public educational program may be warranted. That question need not be decided now.

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[8] D. W. Deno. 1976. Transmission Line Fields, IEEE Trans on Power Apparatus and Systems, Vol. PAS-95(5) : 1600–1611.

[9] State of New York Public Service Commission. Staff Motion to Commission to Approve 765 kV Operating Voltage and Construction. Case 26529, Apr. 12, 1976.

Minimal clearances that will meet the 5.0 mA steady state current limit for all vehicles reasonably anticipated to travel on or across any part of the R/W will be provided by the applicant. No currents above that limit would be experienced from touching a school bus, a milk tanker, a bucket truck or a combine operating on the R/W away from roads. In conclusion, we believe that PSI's present design clearances that maintain a maximum worst possible case induced current of 5 mA rms when the largest anticipated truck, vehicle or equipment under the line is short-circuited to ground for the proposed 765 kV line provide adequate protection from induced shock currents.

II. Biological effects of electric and magnetic fields

The passage of an electric current through any unshielded conductor produces both electric and magnetic fields in the surrounding medium. The effect of electric fields on humans has been and presently still is being studied extensively throughout the world. As transmission designs result in larger and larger voltages, more intense fields that cover wider areas may result. For an overhead AC transmission line, the three separate phases create an interference pattern so that the strongest field exists in the area below the outer phases, approximately 20 to 60 feet from the centerline. The field drops off moderately as one moves closer to the centerline, and falls off rapidly as one moves further away from the facility. A 765 kV facility with a minimum ground-to-conductor clearance of 42 feet produces a peak electric field of 12 kV per meter at ground level, dependent upon conductor configurations, and the field drops off to between 2 and 3 kV/meter at about 150 feet from the centerline. The magnetic field produced by a high voltage transmission line has similar characteristics. The maximum calculated magnetic profile at 1.5 m above the ground is about .6 G (gauss). Safety standards for whole body exposure to magnetic fields for long periods have been recommended at 200 to 300 G.[10] No harmful biological effects are expected from magnetic fields under transmission lines because magnetic field levels at which effects occur are generally much higher than levels under powerlines.

Precautionary electric field guidelines have been established by the Russians for substation and transmission line workers.[11] More recently the Russians established general exposure guidelines for the local population and agricultural workers.[12] Using the Russian general population guidelines, it appears that PSI 765 kV lines can be permitted.[13]

It is our position that additional research needs to be undertaken to determine whether electric fields can cause short and long term biological effects. Current research is being funded and guided by the Federal Interagency Advisory Committee on Electric Field Effects on which NRC Staff actively serves. The Staff recommends that construction of PSI's 765 proposed lines be permitted, and that at the O.L. review stage when additional experimental data has been gathered, the Staff will again review this issue. If experimental data were to warrant protective measures, a variety of actions could be considered including, but not limited to: increasing the width of right-of-way to limit the field strengths to which the public would be exposed of the right-of-way; potential rights-of-way users be given specific warnings of possible risks; use of shield wires or other types of retrofitting techniques which could reduce field gradients to a prescribed level. Thus, protective measures that might have to be taken if, in fact, electric and magnetic fields represent a real hazard may take the form of educational programs, wider right-of-way, possible restrictions on the use of the right-of-way, reduction of operating voltages, and possible engineering techniques to reduce electrostatic fields at ground levels. The pertinent point for the present is that possible protective measures do not include changes in tower design or conductor size or configuration since fields produced by 765 kV lines are similar at the edge of the right-of-way with other electric lines, and even the maximum field strengths for 765 kV lines are of the same order of magnitude as for lower lines (such as a 345 kV line).

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[10] U.S. Department of Interior (Bonneville Power Authority). pp. 17–19.

[11] "Rules and Regulations on Labor Protection at 400, 500, and 750 kV AC Substations and Overhead Lines of Industrial Frequency (in USSR)", 1972. Translated by G. G. Knickerbocker in Special Publication No. 10, Power Engineering Society (IEEE), 1975.

[12] Y. I. Lyskov, Y. S. Emma, and M. D. Stolyarov, 1975. Electric field as a parameter considered in designing electric power transmission of 750–1150 kV ; the measuring methods, the design practices and direction of further research. Trans. by G. G. Knickerbocker in Special Publication No. 10, Power Engineering Society (IEEE), 1975.

[13] This established higher acceptable gradient standards of transmission lines in accordance with these direct quotations (from Lyskov, et al. 1975) :

"In designing the O. H. 750–1150 kV line, considering that cumulative effect of the field due to an infrequent and nonsystematic exposure of the local population and the agricultural workers can practically be disregarded, as permissible magnitudes of the field intensity the following higher standards were accepted :

20 kV/m for difficult terrain.
15–20 kV/m for non-populated regions,
10–12 kV/m for road crossings.

"The permissible field strength must not be exceeded at the center of the span at the height of 1.8 meters above ground and at the lowest sag (at the maximum 15 year temperature).

"The permissible values of field intensity were chosen with consideration of favorable operating experience in over 150.000 km/years in O. H. 500 kV lines, for which the designed field intensity is for similar conditions from 10 to 14 kV/m."

However, a Russian paper by Y. D. Dumanskiy, et al. entitled "Hygienic Evaluation of Electromagnetic Field Generated by High-Voltage Power Lines" (in Gigiyena I Sanitariya–No. 8 :19–23, 1976), just recently obtained by the Staff, states that laboratory test animals (albino rats) undergo changes in behavorial reactions when subjected to fields in the range of only 1 to 5 kV/meter. These field gradient levels are considerably below the general population standards quoted above.

The Staff had not addressed the question of field gradient effects on plant or animal life along the transmission line in the FES for two distinct reasons:

(1) It is our position that any effects attributed to the electric field on humans would generally include animals, since most animals would have a territorial range extending beyond the right-of-way and therefore would not be exposed for long periods to field gradients; those animals which exhibited a more limited range would most likely be shielded extensively from gradients at ground level by surrounding shrubs, grasses, etc., and therefore would not receive a high cumulative dose.

(2) Field tests and studies of biological ill effects of field gradients conducted on plants and animals have been generally inconclusive. For field tests and studies which fall within the range of worst case field gradients below transmission lines (20 kV or less), no significant effects have been attributed to electric fields. The applicant has projected field gradient of 12 kV/m; thus no significant effects are expected.

The Staff did not address the question of electric field effects on agriculturally related plant life in the FES. The Staff has reviewed the latest data on this subject as well as animal laboratory and field studies and summarizes the findings below.

Preliminary results of current research[14] on electric field effects on growth and development of plants and animals indicate that neither gross injuries nor gross abnormalities were apparent from a 50 kV/m field. Some minor physical damage, barely perceivable along corn, bluegrass, and alfalfa leaf tips was indicated in fields from high fields of 25 kV/m and above. The same series of studies investigating electric field effects on small animals indicate that no major abnormalities in behavior, activity, or outward appearance have been demonstrated from high fields of 50 kV/m. The preliminary results further substantiate published data which to date have not indicated any hazardous effects to laboratory and agricultural animals from present levels of field generated from existing transmission power line technology.[15]

Based on these findings, the Staff does not believe that changes in the applicant's proposed design are warranted. As in the case of human ill effects, additional extensive studies are presently being conducted. The Staff is keeping abreast of these studies and of any guidelines resulting from them, and will reconsider the impacts of the transmission line operation prior to or at the time of the operating stage review, taking into consideration any new information.

Senator STEVENSON. Before we get off the subject, you mentioned toxic gas. That's a new one for me. What are the toxic gases associated with these transmission lines?

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[14] The Effects of High Voltage Electric Lines on the Growth and Development of Plants and Animals. J. W. Bankoski, A. B. Graves, and G. W. Meku. Proceedings of the First National Symposium on Environmental Concerns In Rights-Of-Way Management. Mississippi State University. 1976.

[15] Biological Effects of High Voltage Electric Fields: State-of-the-Art Review and Program Plan. IIT Research Institute, Chicago, Illinois. November 1975.

Mr. PETERSON. It is primarily ozone, Mr. Chairman, which is triatomic oxygen (O_3). It is formed by the high voltage field; and it is very common, for example, in the area after a thunderstorm. You have the same type of electrical activity.

Senator STEVENSON. Is it toxic?

Mr. PETERSON. Yes, sir. It is very chemically reactive. The ozone levels that have been found around powerplants and transmission lines do not appear to be a health hazard at this time. The main hazard, according to what we have looked at, seems to be the induction of electric shock due to buildup of static electricity on metal structures.

Senator STEVENSON. Including the supports for transmission lines?

Mr. PETERSON. Including the supports for transmission lines; yes sir. They are grounded anyway.

Senator STEVENSON. You mention toxic gases around the generating plant, but they could be generated at any point in that corridor?

Mr. PETERSON. Yes, sir. If there is a spark discharge or static electricity discharge. Again, the powerlines are very carefully designed to minimize this potential problem. It does not appear to be a health problem at this time. Those are the types of things we do examine in preparing the environmental impact statement.

Senator STEVENSON. Let's say it is not a nuclear generating plant but a coal-fired generating plant.

Mr. PETERSON. The same problems would exist.

Senator STEVENSON. The President's energy program aims at converting to coal from other fossil fuels and to some extent from dependence on nuclear energy; do you have the same problems? Is anybody regulating that aspect of the siting or the construction of coal-fired generating plants?

Mr. PETERSON. Not to my knowledge.

Senator STEVENSON. Not to your knowledge? Is that correct, Mr Gossick?

Mr. GOSSICK. That is correct.

Senator STEVENSON. In your regulation of the nuclear-powered plants, have you on many occasions had to require design changes, make requirements that would not otherwise have been met in order to assure safety?

Mr. GOSSICK. On this particular point I think not many changes, but there are in fact some changes that have been required of the licensees.

Senator STEVENSON. No one is making those requirements in connection with the coal-fired plants?

Mr. GOSSICK. Not to my knowledge; no, sir.

Senator STEVENSON. How should that subject or aspect of the problem, the coal-fired and the other energy-producing processes be regulated? Should they be brought within the NRC? Should EPA be given a mandate?

Mr. GOSSICK. I would not suggest that this is a problem area that should be addressed by the NRC. I think it is a problem, however, that either the EPA or the new Department of Energy, or some Federal agency, should address and perhaps in cooperation with the States decide whether this is a matter to be handled at the Federal level or perhaps at the State level, Mr. Chairman.

Senator STEVENSON. Well, I would think so.

As I was saying earlier, it is difficult for people to have confidence in the operation of the NRC hearing what they hear, not knowing what to believe. Confidence was strained again recently when it was reported that 280 pounds of weapons' grade uranium had been "lost" from the Apollo, Pa., facility. Mr. Gossick, are these reports accurate? What happened to the 280 pounds of uranium; and if they are accurate, what is NRC doing to find the uranium?

Mr. Gossick. Mr. Chairman, the report to which you make reference—articles in the Saturday Washington Post, and I believe the Sunday Star—had to do with a facility where there has been an operation dealing with nuclear materials, high-enriched uranium, since about 1959. There are one or two other such plants——

Senator Stevenson. Could I make the same request, that you speak more closely to that microphone. I hope it is on.

Mr. Gossick. Yes, sir, it is on.

There are a number of such facilities in the United States that over the years have been involved primarily in the Navy's submarine program and in producing fuel for the submarines, and they have dealt with this sort of material. The term "material unaccounted for"—a term which generally gets translated to "lost" or in some cases "stolen"— reflects a problem that is encountered in the chemical processing of this material. The difficulty lies in measuring exactly how much you have in any given part of the process of fabricating the material—being able to measure scrap, being able to detect and account for small quantities of material held up in pipes, held up in the various processes.

Over the period of years, there have been a number of instances where material was listed as unaccounted for. In more recent years, we have required an ever-tightening process for measuring, for taking inventory, and for reporting to the Nuclear Regulatory Commission, and before that to the AEC, any measurements by the licensee, and these are checked by our inspectors when this material is not all accounted for.

The problem here is one of accounting. To our knowledge we have no evidence to lead us to believe that this material has literally been made away with and used for illicit purposes. We don't depend on material accounting as the only way of assuring ourselves that that is the case. Our safeguards program is a combination of accounting for this material, keeping control of it where it is, plus a rigorous physical security program that involves guards and security measures which would prevent someone from literally making off with the material.

Over the last 2 or 3 years, as increased attention has been given to the safeguarding of this material, we have been increasing our requirements on the licensees.

This applies not only to the kind of facilities that we are speaking of here, those dealing with high-enriched uranium, but to those using material of all kinds that could be used for illicit purposes.

We also have been increasing the requirements for protection against sabotage of the nuclear reactors.

We have just recently put into effect increased requirements for those plants.

Just this past week the Commission has approved the issuance for public comment and for further rulemaking a requirement for further tightening the physical security requirements at licensed nuclear fuel cycle facilities. Those rules will be going into effect after they have gone through the hearing process.

Senator STEVENSON. Is that a unique occurrence? Have there been other such experiences, such discrepancies, losses of uranium?

Mr. GOSSICK. There have been from time to time other events or other incidents where we list material unaccounted for.

In fact, it is almost the unusual occurrence when, on an inventory, the balance is zero. In other words, the licensees seldom measure actual material on hand and come out exactly with the material that their books say is in the plant. Sometimes it's over; sometimes it's less. It usually varies within a small range. On one or two occasions there have been larger discrepancies that, after thorough investigation by our inspectors and investigators, we have been able to account for. In some cases the material has been discarded with scrap or put in some place where it was later found. In some cases——

Senator STEVENSON. Discarded with scrap?

Mr. GOSSICK. With scrap, but not off the premises. It has been kept within the plant but not accounted for, not measured as part of the scrap that was resulting in the process.

Senator STEVENSON. You said in larger numbers? Have there been larger losses of enriched uranium?

Mr. GOSSICK. No. No. I said there have been occasions where there have been significant numbers in terms of kilograms.

Senator STEVENSON. Can you give us those numbers?

Mr. GOSSICK No, sir, I cannot.

Senator STEVENSON Have you got those numbers?

Mr. GOSSICK Yes, sir, we have. NRC and ERDA are in the process now, Mr. Chairman, of producing, at the request of the GAO and Mr. Dingell's committee in the House, a complete rundown on all of the material unaccounted for.

ERDA has responsibility for producing the information up until 1968. At that time, the safeguards responsibilities for these licensed facilities were placed under the purview of the AEC regulatory staff—now the NRC.

All of those numbers are presently considered as classified. They will be released sometime in August. They will be released for material up to 6 months old.

In other words——

Senator STEVENSON. Won't go back more than 6 months?

Mr. GOSSICK. It will go back beyond 6 months. Anything in that regard that has happened in the last 6 months will not be released.

Senator STEVENSON. When it is available in August will you give us a copy?

Mr. GOSSICK. Yes, sir.

Senator STEVENSON. If I understood you correctly, most of this is material unaccounted for and it is due to management problems. You also said, I understood you, that it could be stolen? Was stolen in some instances?

Mr. GOSSICK. To our knowledge, Mr. Chairman, the material based on the investigations——

Senator STEVENSON. I don't mean just this particular 280 pounds. In that or in other instances. Do you have any evidence to indicate there were thefts?

Mr. GOSSICK. No, sir, we do not.

Senator STEVENSON. You just don't know?

Mr. GOSSICK. We don't know. That is correct. In view of the investigations that have been conducted, coupled with the physical security measures that we have imposed, it is our belief that no material has been stolen.

Senator STEVENSON. Isn't some of it lost in the processing? Doesn't it sometimes escape as leaks of gaseous or liquid uranium compounds?

Mr. GOSSICK. To a certain extent that is true. There may be small effluent releases that are either gaseous or liquid. Those are monitored, and generally represent a very small part of the problem of accounting for this material.

Senator STEVENSON. Isn't that one of the explanations of the Apollo factory? Leaks of gaseous compounds? Didn't they expose workers to high levels of radioactivity?

Mr. GOSSICK. As I understand it, there was a time when radioactive gaseous effluents resulting from the processes were higher than what we felt was desirable or necessary, although I believe they were within regulatory limits.

Again, I think these releases probably represented a very small portion of the loss or the unaccounted for category materials.

Senator STEVENSON. Have steps been taken at that facility to prevent a repetition of such exposures?

Mr. GOSSICK. We have had a series of upgrading actions. We have had inspectors at that plant almost on a continuous basis for the last several months. It is an old plant. There are certainly inherent difficulties in bringing it to the standards you would expect if you were going to build a new plant today.

The licensee has been responsive in taking those actions that we deem necessary to improve the situation there.

Senator STEVENSON. How many workers were exposed?

Mr. GOSSICK. I don't have that number. I can get it for you for the record, Mr. Chairman.

Senator STEVENSON. Thank you.

[The following information was subsequently received for the record:]

OVEREXPOSURES AT APOLLO, PA FACILITY AS OF JULY 1, 1977

1974—17 reported overexposures (7 of less than 70 hours at the maximum permissible concentration (MPC); 4 in the range of 70–150 MPC hours; 6 of more than 150 MPC hours).

1975—11 reported overexposures (6 of less than 70 MPC hours; 5 in the range of 70–150 MPC hours).

1976—6 reported overexposures, all less than 70 MPC hours.

1977—No reported overexposures.

Senator STEVENSON. You have indicated a number of occasions that security precautions are being taken, security measures have been tightened up. I visited a storage facility once where spent fuel rods were kept underwater in large galvanized steel buildings with what seemed to me to be very inadequate security measures.

There were very few guards, and the buildings could easily have been penetrated. What concerned me the most was the transportation of the spent fuel rods to this facility. They rolled in on the back of flatbed trucks in those steel cylinders with no guards. The drivers didn't even have radios in those trucks.

Can you tell us a little about what security precautions and measures are in force now with respect to the transportation of spent fuel rods?

Mr. GOSSICK. We have recently increased the requirements in the transportation of special nuclear material. However, NRC's physical security regulations do not require guard escorts in the transportation of spent fuel because of the substantial protection afforded by spent fuel shipping casks and by the inherently hazardous nature of the material against removal or diversion of terrorist acts. I would like to ask Dr. Mattson to speak, one, to the hazard involved in the spent fuel rods and the material involved, and also to the additional measures that have been taken.

Senator STEVENSON. They could be stolen. They could be used by irrational people for unpredictable purposes with effects that could be dangerous.

Dr. MATTSON. Two elements to the question:

One, physical security for unirradiated special nuclear material in transit has been increased recently, as Mr. Gossick has explained.

Second, the spent fuel rods are extremely hazardous. You can't physically put your hands on them without doing serious harm to yourself. The material in those spent fuel rods would be extremely difficult to put in the form of a weapon.

Senator STEVENSON. All I am saying is this world is full of mad people. We ought to anticipate insanity.

Dr. MATTSON. Yes, sir.

Senator STEVENSON. What are the precautions and security measures that are now being taken with respect to the transportation?

Dr. MATTSON. The upgraded rule Mr. Gossick has referred to will be published in the Federal Register within the next week. It speaks to a significant increase in the number of guards.

Senator STEVENSON. On the trucks?

Dr. MATTSON. Yes, sir. The escort vehicles, communications, their arms, their training. They are all being increased significantly. The number of guards will go up to like nine.

Senator STEVENSON. The trucks that I saw had zero guards.

Dr. MATTSON. That was some time ago.

Senator STEVENSON. That was not very long ago.

Dr. MATTSON. It was increased in the early 1970's, 1972, 1973. This will be even more.

Senator STEVENSON. I took my trip to this facility since then. I hesitate to tell you where it is.

Mr. GOSSICK. I think I know where it is.

Dr. MATTSON. Our regulations permit decreasing the amount of security required when shipping spent fuel because of the protection afforded by the casks in which the fuel is shipped. That is, it would be darn near impossible to cause radioactive release that would be of consequence to people because of the size of the casks, the scale of their construction for safety purposes. That may explain what you saw, sir.

Senator STEVENSON. That is what I saw. I won't prolong this. We are getting a little off the subject.

As a former tank commander, I am not altogether unfamiliar with the means by which such metal containers can be penetrated. They can be. That is a great difficulty.

In fact, it is a whole lot easier to do it now than when I was a tank commander.

We will have some further questions including questions on these transportation problems. Let me ask one more if I may, and we will move on.

Mr. Gossick, you said that 80 percent of your fiscal year 1978 research funds will go to reactor safety research, 12 percent to environmental and fuel cycle research, and 8 percent to safeguards research.

What criteria does NRC use to allocate these funds, and in particular are adequate resources being devoted to safeguards research including radioactivity research, and that reminds me of another question I meant to ask: are you conducting research on the effects of nonionizing radiation?

Mr. GOSSICK. No, sir, we are not. We are not doing research in that area.

Senator STEVENSON. Is, in your opinion, adequate research being done by other agencies on nonionizing radiation?

Maybe Dr. Peterson would like to speak to that?

Mr. GOSSICK. I think our general opinion would be yes, it is adequate, in general terms. I don't think we can get terribly specific about the levels in each area. I think generally it is.

Senator STEVENSON. Let's get back to the question.

Mr. GOSSICK. Let me take the latter part of it first.

I believe that the funds that we are requesting of Congress—have received this current year from Congress for our research activities—are adequate to do the kinds of things that we deem necessary.

As to the criteria by which we determine how much goes to reactor safety research as opposed to the other areas, I think one must recognize, of course, that when NRC came into being there was, in fact, a large reactor safety research program getting underway or already underway. We have in that program some $70 or $80 million, some rather large hardware kind of projects, such as the loss-of-fluid test facility that we have at Idaho Falls.

This is to simulate a pipe break, simulate a loss-of-coolant accident in a reactor. Those programs have been expensive and are now at the stage where testing has begun, and so they account for a fairly sizable part of the reactor safety research program.

Most of our work is in the light water reactor safety area. We do spend some portion of our reactor program in advanced reactors, dealing with gas cooled as well as the breeder.

The health and environmental, fuel cycle, and safeguards programs are of more recent origin, having literally been formulated by the NRC working with other agencies as appropriate in the last 2½ years that we have been in existence.

Again, to answer your question, in our view—and the authorizations committees dealt with this in some detail—we think that the levels we requested and hope to get for safeguards research will be adequate as in the environmental and other fuel cycle areas.

Senator STEVENSON. Thank you, gentlemen. We will have some further questions for you.

Thank you very much.

[The statement and material referred to follow:]

STATEMENT OF LEE V. GOSSICK, EXECUTIVE DIRECTOR FOR OPERATIONS, U.S. NUCLEAR REGULATORY COMMISSION

Mr. Chairman, I am pleased to have this opportunity to speak with the Committee on the subject of radiation protection. I understand that your primary interest is the adequacy of current research and regulatory efforts. Essentially all of the activities of the Nuclear Regulatory Commission fall within that area of interest. The Commission is responsible for the licensing and regulation of nuclear materials and facilities, including nuclear power plants, under the provisions of the Atomic Energy Act of 1954, as amended. We see to it that such facilities are properly located, designed, constructed and operated to protect people against the hazards of radiation leakage or accidents. We also assure that people and the environment are protected from possible hazards arising from the storage, handling and transportation of nuclear materials used in research reactors and laboratories, hospitals, and industry.

The NRC came into existence in 1975, under the terms of the Energy Reorganization Act of 1974. Because of this relatively short history, many of our research programs and some of our regulatory programs are new and still developing. However, we have in place today definitive and proven effective programs for protecting workers and the public from exposures to radiation arising from the routine operation and anticipated incidents associated with the production of electricity by nuclear power. In the short time available to me today I will try to summarize our research program and the other work we see remaining to be done in radiation protection. Some of this work will fall under our present authority—some may not. More detailed and quantitative information in our programs and resources has been provided in response to your written questions. I will not repeat that material here.

I. STATUS OF RESEARCH

The Energy Reorganization Act of 1974 provided for research ". . . which the Commission deems necessary for the performance of its licensing and related regulatory functions." Such supportive research is of a confirmatory nature as differentiated from development of reactor or safety system designs.

Despite the fact that radiation is probably the most studied of any potential occupational hazard or environmental impact, we continue to identify areas where the available scientific and engineering information is less than desirable for regulatory decisions. These gaps in knowledge generally can be filled by research or by the collection and analysis of operating data obtained over a period of time. In licensing actions where gaps in knowledge are known to exist, we can make conservative assumptions pending the results of research. Thus, in the long run, once the results of confirmatory research are available, they generally permit better definition of a margin of safety and appropriate adjustment or removal of conservatism in subsequent licensing actions.

We have requested about $130 million for the NRC research program for FY 1978. About 80 percent will go to Reactor Safety Research, 12 percent to Environmental and Fuel Cycle Research, and 8 percent to Safeguards Research. Of the Reactor Safety Research funds, 80 percent will be spent on light water reactors and 20 percent on advanced reactors.

Essentially all of our Reactor Safety Research Program concerns the mechanical and physics aspects of reactor engineering. For example, the program includes research in nuclear physics, fluid mechanics, heat transfer, fuels behavior, systems analysis methods, strength of materials, and natural phenomena such as earthquakes and tornadoes. This research is supportive of technical areas in licensing reviews. Much of the research money in this area goes to the performance of large scale safety related experiments and tests of nuclear system prototypes and components.

Some of the Fuel Cycle and Environmental Research Program parallels the one for reactors, being oriented to the mechanical and physics aspects of nuclear fuel facilities, such as uranium milling, fuel fabrication, chemical processing, transportation, and waste management. Other elements of this program particularly germane to this hearing involve analysis of the movement of radioactive materials in the environment, interaction of radiation with plants and animals, and effects of ionizing radiation on people—including potential health effects from occupational exposures and from environmental levels of radioactivity. This research program includes epidemiological studies of the effects of low level radiation exposures. This work is relatively new for NRC, and it closely tracks the larger, more broadly based, and more basic research programs of the Energy Research and Development Administration and the National Cancer Institute.

II. NEW TECHNOLOGIES WHICH MAY PRODUCE RADIATION HAZARDS

The Committee has asked whether we are aware of new or emerging technologies which are likely to produce new radiation hazards. We are not. However, there are a number of known radiation sources of potential concern which require more attention than previously afforded. Two examples of such sources of current concern to NRC are naturally occurring radioactive materials and accelerator produced radioactive material, neither of which are currently subject to NRC regulations. In these areas, the objective should be to assure that all radiation exposure, whether it arises in medical, commercial, industrial, military, or power production activities is controlled with a uniformly applied, prudent public health policy derived from consistent application of the extensive base of scientific information on radiation effects.

Because of this concern and in response to requests by some States and by the Conference of Radiation Control Program Directors, the Commission directed a task force to study the matter of the need to regulate the use of naturally occurring materials and accelerator produced materials and to present findings with respect to the adequacy of existing regulations. This task force has recently completed a draft report which is being reviewed within NRC. The task force found that authority to regulate naturally occurring and accelerator produced radioactive materials by State and Federal Govrenments is fragmented among many departments, commissions, and agencies which overlap in some areas and leave gaps in others. Thus, it is difficult to know in an overall sense whether balanced and comprehensive protection is being provided to all workers and to the public. The task force recommended that the NRC seek legislative authority to regulate these materials because they present significant radiation exposure potential and because of the fragmentary and non-uniform controls now available. Reviews and formal views on this matter will likely be sought by the Commission from other Federal and State agencies as well as from the general public. The task force report should be available to the public within a few weeks.

III. COOPERATION AMONG FEDERAL AGENCIES WITH RESPECT TO CURRENT RESEARCH PROGRAMS AND REGULATIORY EFFORTS

The Committee also asked about interagency cooperation. We find that there is a considerable degree of cooperation among Federal agencies, between Federal and State agencies, and on an international scale. This is particularly true where the expertise in a specific agency is useful and important to others in fulfilling their responsibilities or when one agency or government issues regulations which will have a substantial impact on the operation of others. The historic basis for this cooperation has two aspects, scientific and management The scientific cooperation was fostered by the broad expertise and influence of scientific advisory bodies such as the International Commission on Radiological Protection and the National Council on Radiation Protection and Measurements. The management coordination was originated by the former Atomic Energy Commission in its approach to international and States programs. This policy emphasis has been continued by NRC. Elsewhere within the Executive Branch, the Office of Management and Budget and the Environmental Protection Agency have taken important management coordination roles in radiation protection matters in recent years. While there is considerable cooperation owing to these efforts, there is always room for improvement to produce more efficient regulation of commercial or research applications or radioactive material or radiation devices without decreasing protection of the health and safety of the public and radiation workers.

Among the areas where improvement is currently needed are (1) clearer definitions of limits of authority among agencies; (2) requirements for analysis of the net value of proposed regulations including the effects of their implementation; and (3) guidelines for judgments in the acceptability of risks. We believe that some consolidation of Federal radiation activities would speak to these needs for improvement and could result in a reduction of duplication, particularly in the lines of authorities of EPA and NRC. Of course, any consideration of adjustments of authority within the Federal government also could consider the important related issue of the alignment of authority between the Federal government and the States.

For the present, there is some lack of balance in radiation protection and some costly duplication of efforts. The role played by the Environmental Protection Agency, within the current alignment of radiation protection responsibilities, is central to achieving needed improvements. For example, in the exercise of authority transferred from the now defunct Federal Radiation Council under Reorganization Plan No. 3, the EPA could assure uniformity and balance in radiation protection activities among Federal agencies. For example, this authority now assures that workers with medical x-ray machines and others working with cobalt irradiators are required to be protected to the same degree, even though responsibilities for regulation of the two types of devices reside in several places outside of EPA.

Similarly, EPA has authority to establish radiation standards for the general environment. In exercise of this authority it could also draw upon its expertise and authority in other areas to provide even-handed treatment of a variety of industrial pollutants to assure an overall optimization and balance in expenditures to protect the environment. Or, as another example, EPA could assure that the limits on environmental effects of radioactive hospital effluents were given balanced treatment in light of the strict environmental limits now applied to the nuclear fuel cycle.

The NRC is supporting EPA's efforts in exercise of these two overriding, umbrella-like authorities for radiation standards. Such standards assure balanced requirements for control of environmental pollutants and hazards in the work place. We place particular emphasis on coordination in the development of EPA's environmental radiation standards. The inclusion of important NRC implementation concerns in EPA's recently issued regulation (40 CFR Part 190) for the uranium fuel cycle is an example of interagency coordination to reduce its regulatory burden at no cost to environmental protection. Similar cooperation is needed and planned in connection with environmental radiation standards now being developed by EPA for radioactive waste management activities.

IV. REGULATING EXPOSURES OF INDUSTRIAL WORKERS TO IONIZING RADIATION

The Committee has expressed a special interest in the protection provided for radiation workers. In the remainder of this statement I will concentrate on this area since it of high priority to the Committee, and it illustrates the general philosophy and policy direction of the Commission in all radiation protection matters.

Several years ago the Commission became aware of the generally rising trend of occupational radiation exposures at nuclear power plants and took positive action to achieve more effective controls. We accomplished this through a system of regulation which requires that prescribed levels of protection be provided by licensees for their workers, and that unnecessary exposures below these limits be eliminated. Prior to 1971 the practice was simply to require compliance with the radiation protection limits in our regulations. After several years of experience with this approach it became evident that workers were receiving radiation exposures which were within the limits, but which, in some instances, could be further reduced with relative ease and at reasonable cost.

Exposure reductions appeared to be readily achievable through better facility and equipment designs, better worker training, and better operating procedures. Additional exposure reduction was considered desirable because of the Federal radiation protection policy to assume that some degree of risk is associated with any radiation exposure, however small. Therefore, in January 1971, Title 10 of the Code of Federal Regulations, Part 20, was amended to require licensees to assure that levels of exposure were not only within the limits but "as low as practicable." This approach is now well along in the implementation phase.

The first major step in implementing this approach was the issuance of a regulatory guide on occupational exposure control at nuclear power plants. These facilities were chosen for this first effort because of the large number of workers employed and exposed in their operation, and the record of high occupational exposures, both individually and collectively, especially during maintenance operations. After this guide was issued there were marked design and operational improvements. The guide has been recently expanded to better chronicle the favorable results and design approaches accomplished by industry design experts. I have a copy here which I would like to have entered in the record of this hearing. We are confident that this sort of guidance will lead to further exposure reductions across the full spectrum of facilities and activities regulated by NRC. For example, a similar guide will be issued for medical institutions within the next few weeks.

Operators of nuclear power plants have found that there is often an economic advantage to eliminating unnecessary radiation exposures, particularly through improved designs. The reason for this is quite simple, although it has only recently begun to be fully appreciated. First of all, operations must be conducted within NRC dose limits, and if it is necessary to bring in extra workers to complete a task without exceeding the limits, then the results are higher costs. These costs may be avoided and the unacceptable practice of large cumulative doses being spread out over a large number of workers can be eliminated, if the design of the plant provides radiation protection sufficient to make the use of extra workers unnecessary. Nuclear power plant operators have become acutely aware of these facts as the first generation of commercial nuclear power plants mature and require maintenance. These lessons definitely are being fed back into the design of future plants.

We are now placing additional emphasis on the concept of eliminating unnecessary occupational radiation exposures in all licensed activities thus extending the experience we have gained in reactor applications. A plan of action was adopted by the Commission in February 1977, which will strengthen this aspect of our program across the full sweep of activities which we regulate. The major elements of this plan will require licensees (a) to develop written exposure control programs; (b) to meet minimum training requirements for workers, and special criteria for temporary workers; and (c) to employ radiation protection personnel of demonstrated competence in both the design and the operational phases of the nuclear facilities. Within NRC, the plan calls for independent study of methods to reduce exposures in licensed facilities and methods for reducing the amount of required maintenance or contaminated equipment. Based on our considerable experience in controlling occupational exposures and on the recent successes of our initial implementation of these regulatory concepts with nuclear power plants; we are confident that this program will succeed.

Mr. Chairman, we appreciate the opportunity to present the views and the program of the Nuclear Regulatory Commission in this important public health and safety area. We are prepared to respond to your questions.

Revision 2
March 1977

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

FOR COMMENT

REGULATORY GUIDE 8.8

INFORMATION RELEVANT TO ENSURING THAT OCCUPATIONAL RADIATION EXPOSURES AT NUCLEAR POWER STATIONS WILL BE AS LOW AS IS REASONABLY ACHIEVABLE

A. INTRODUCTION

Paragraph 20.1(c) of 10 CFR Part 20, "Standards for Protection Against Radiation," states that licensees should make every reasonable effort to maintain exposures to radiation as far below the limits specified in that part as reasonably achievable. This guide provides information relevant to attaining goals and objectives for planning, designing, constructing, and operating a light-water reactor (LWR) nuclear power station to meet the criterion that exposures of station personnel[1] to radiation during routine operation of the station will be "as low as is reasonably achievable" (ALARA). Major accident situations and emergency procedures are not within the scope of this guide.

Much of the information presented in this guide also is applicable to nuclear power stations other than those cooled with light water. The applicable goals and objectives should be used for all nuclear power stations until more specific goals and objectives are available for other types of power reactors.

B. DISCUSSION

The relationship between radiation dose and biological effects is reasonably well known only for doses that are high compared with current annual dose limits and only when such doses are delivered at high dose rates.[2] An ad hoc committee of the National Council on Radiation Protection and Measurements (NCRP) (Ref. 1) chose in 1959 to make the cautious assumption that a proportional relationship exists between dose and biological effects and that the effect is not dependent on dose rate. Essentially, this amounts to an assumption of a non-threshold, "linear" (straight line) dose-effect relationship.

The International Commission on Radiological Protection (ICRP), the Federal Radiation Council (FRC), and committees of the National Academy of Sciences/National Research Council (NAS/NRC) have used this hypothesis to estimate conservatively the number of possible biological effects that statistically may be associated with exposures to radiation.

The NAS/NRC Biological Effects of Ionizing Radiation (BEIR) Committee (Ref. 2) reiterated that the assumption of a non-threshold linear relationship between dose and biological effects independent of the dose rate should be applied for radiation protection purposes. The radiation protection goal is to reduce doses wherever and whenever reasonably achievable, thereby reducing the risk that is assumed (for radiation protection purposes) to be proportional to the dose.

Merely controlling the maximum dose to individuals is not sufficient; the collective dose to the group (measured in man-rems) also must be kept as low as is reasonably achievable. "Reasonably achievable" is judged by considering the state of technology and the economics of improvements in relation to all of the benefits from these improvements. Under the linear non-threshold concept, restricting the doses to individuals at a fraction of the applicable limit would be inappropriate if such action would result in the exposure of more persons to radiation and would increase the total man-rem dose.

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[1] "Station personnel," as used in this guide, includes all persons working at the station, whether full-time or part-time and whether employed by the licensee or by a contractor for the licensee.

[2] Throughout this guide the word "dose" will allude to "dose equivalent," the term used for radiation protection purposes, with the unit expressed in "rems."

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. However, comments on this guide, if received within about two months after its issuance, will be particularly useful in evaluating the need for an early revision.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

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The radiation protection[3] community has recognized for many years that it is prudent to avoid unnecessary exposure to radiation and to maintain doses ALARA. In addition to reduced biological risks, the benefits of such practices may include avoidance of costs for extra personnel to perform maintenance activities and avoidance of non-productive station shutdown time caused by restrictions on station personnel working in radiation areas.

Annual collective radiation dose equivalents received by personnel working at an LWR nuclear power station have ranged from less than 100 man-rems to over 5,000 man-rems (Refs. 3 and 4). Typically, annual collective dose equivalents range from 400 to 1,000 man-rems at LWR stations that have been in operation from 2 to 14 years and have generating capacities ranging from less than 100 MWe to 800 MWe. In view of the anticipated growth of nuclear power stations over the next few decades and the radiation exposure experience to date, additional efforts to reduce radiation doses to nuclear power station personnel are warranted.

The wide range in collective radiation doses to station personnel among the various stations appears to be primarily a function of doses received in maintenance operations in radiation areas. Some data are available to permit estimates of the distribution of doses among broad job categories and among the equipment systems or components that represent substantial sources of exposures. Doses to station personnel are influenced by many variables, including the ability of fuel elements to retain fission products, the extent of deposition of activated corrosion products throughout the primary and auxiliary coolant systems, the reliability of other specific equipment, the station layout, and radiation protection programs.

If design reviews or inspections had revealed that radiation exposures at nuclear power stations were unavoidable or that the cost of reducing the exposures would be unreasonable, the exposures might be considered ALARA by definition. However, this has not generally been the case. In many instances, poor supervisory practices or radiation protection inadequacies of one kind or another have been recognized as contributing factors to unnecessary exposures.

A major portion of the radiation exposure of station personnel is received during maintenance, radwaste handling, inservice inspection, refueling, and nonroutine operations. The decommissioning process also has a potential for substantial exposures to personnel. Effective design of facilities and selection of equipment for systems that contain, collect, store, process, or transport radioactive material in any form will contribute to the effort to maintain radiation doses to station personnel ALARA.

Products of erosion or corrosion (i.e., "crud"[4]) that become mobile and are activated constitute an important (perhaps principal) source of radiation with respect to the exposure of station personnel. (Crud is accumulated in and transported by the coolant. Some components of the crud become radioactive when passing through the reactor core. Migration of crud to other systems occurs with coolant or steam. Specific radionuclides that have been identified in crud and that can contribute substantially to the radiation source are Co-58, Co-60, Mn-54, Zn-65, and Zr-95.)

Exposures of station personnel who service equipment contaminated by crud can generally be reduced substantially by minimizing the formation of crud and by designing or modifying equipment to minimize locations where crud can deposit and accumulate. Provisions for isolating components and flushing with crud-removing fluid, such as demineralized water, can often reduce accumulations prior to activities such as maintenance or equipment replacement.

Station and equipment layout also can affect the potential for radiation exposures. Exposures at sites where multiple radiation sources exist sometimes can be reduced by additional separation of individual sources. Adequate space for ease of maintenance and other operations can permit the tasks to be completed more quickly, thereby reducing the length of exposures. Shielding by structural materials, equipment, and auxiliary or permanent shields can reduce exposures by isolating radiation sources. Where equipment components constitute a substantial radiation source that cannot be effectively reduced in-place, features that permit the removal of such components for maintenance at remote locations often can be effective in reducing exposures. The use of remote-handling features also can reduce exposures of station personnel in certain instances.

Station technical and supervisory personnel, working closely with radiation protection personnel, can reduce exposures by planning activities of personnel who must enter radiation areas, by studying the actions and procedures of individuals working in such areas, and by conducting post-operation debriefings on projects resulting in substantial exposures to identify how procedures might be modified to reduce exposures on subsequent similar tasks. Training programs for all station personnel can establish and reinforce the principles of radiation protection as applied to specific job functions. By making personnel aware of the methods and the special equipment and protective equipment available to them, potential radiation doses can be reduced.

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[3] The term "radiation protection," as used in this guide, is considered to be synonymous with the term "applied health physics"; i.e., the development and implementation of methods and procedures necessary to evaluate radiation hazards and to provide protection to man and his environment from unwarranted exposure.

[4] "Crud" is corrosion and erosion products and other solids that are formed by chemical and physical reaction between the reactor coolant and structural materials.

The concept of maintaining occupational radiation exposures ALARA does not embody a specific numerical guideline value at the present time. Rather, it is a philosophy that reflects specific objectives for radiation dose management in

(1) Establishing an ALARA program;
(2) Designing facilities and selecting equipment;
(3) Establishing a radiation control program, plans, and procedures; and
(4) Making supporting equipment, instrumentation, and facilities available.

When an adequate data base, including economic information, is available, the criteria for keeping annual collective doses to station personnel ALARA might be derived or selected in numerical terms. However, a data base of operating experience and cost information to provide quantitative guidance for establishing such criteria is not available at this time, and the criteria for meeting the provision of § 20.1(c) of 10 CFR Part 20 must therefore take the form of qualitative guidance (e.g., goals, objectives, and statements of good practice).

The NRC staff has not performed a cost-benefit analysis for each of the considerations discussed or presented in Section C of this guide. This guide presents goals and objectives that were selected to satisfy the principles of the ALARA philosophy and criteria. Attaining these goals and objectives will require good engineering judgment on a case-by-case basis. A cost-benefit analysis may be helpful in arriving at the judgment, but it should not be the decisive factor in all cases.

The nuclear steam supply system (NSSS) vendor, the designer, the architect-engineer (A/E), the constructor, and the operator of the nuclear power facility each have responsibilities related to the ALARA effort; thus, coordination and cooperation are essential to achieving the ALARA goals and objectives.

This guide is written primarily for the applicant or licensee. However, the designer, the A/E, and the constructor will find many of the guide's considerations helpful in the design and construction process to ensure that their efforts are consistent with the needs of the applicant or licensee to maintain radiation exposures ALARA.

Specific design or operational objectives for maintaining radiation exposure ALARA are suggested by the parameters that determine the magnitude of doses to station personnel, both as individuals and as a group. Doses to personnel in nuclear power stations are predominately from external exposure, i.e., from radiation sources external to the body. However, there also exists a potential for doses from internal exposures, i.e., from radioactive materials taken into the body.

Important parameters in determining doses from external exposures are (1) the length of time that the receptor remains in the radiation field and (2) the intensity of the radiation field. Some degree of exposure of station personnel cannot be avoided during the operation and maintenance of nuclear power stations. However, there are many ways by which the exposures and resultant doses can be minimized by reducing the time interval of the exposure and the intensity of the radiation field. The intensity of the radiation field is determined by (1) the quantity of radioactive material, (2) the nature (i.e., characteristics) of the emitted radiation, (3) the nature of the shielding between the radiation source and the receptor, and (4) geometry (e.g., distances and dimensions).

Parameters important in determining doses from internal exposures are (1) the quantity of radioactive material taken into the body, (2) the nature (isotopical and body deposition characteristics) of the material, and (3) the time interval over which the material is retained by the body. The principal modes by which radioactive material can be taken into the body are (1) inhalation, (2) ingestion, (3) adsorption, and (4) injection through wounds. At nuclear power stations, radioactive materials are generally confined, but some dispersion within the station is unavoidable and constitutes the source of (1) contaminated air and liquids that present the potential for intake by inhalation and adsorption and (2) contaminated surfaces that present the potential for intake by ingestion and through cuts or abrasions in the skin. Adsorption generally is not an important intake mode at nuclear power stations except for tritium, which is available for adsorption through the skin.

Consequently, the basic variables that can be controlled to limit doses from internal exposures are those that limit (1) the amount of contamination, (2) the dispersal of the contamination, and (3) the length of time that personnel must spend in contaminated areas. Protective equipment can keep the intake of the contaminant to a minimum. Physical and chemical methods can be used to hasten the elimination of radioactive material taken into the body; however, because of the risks associated with the use of these methods, they are reserved for very serious cases where the probability of experiencing biological effects is quite substantial, e.g., large intakes such as those that might occur in serious accident situations.

ALARA objectives stated in this guide are derived by considering the parameters that affect dose, the variables that exist in the station design features, and the variables that can be provided by station administrative actions. Section C, Regulatory Position, states objectives in a manner that encourages innovation by permitting considerable flexibility on the part of the utility, the NSSS vendor, the designer, the constructor, and the architect-engineer. However, the Regulatory Position also describes a large number of specific concerns that should be addressed in meeting the goals and objectives.

C. REGULATORY POSITION

The goals of the ALARA effort are (1) to maintain the annual dose to individual station personnel as low as reasonably achievable and (2) to keep the annual integrated (collective) dose to station personnel (i.e., the sum of annual doses (expressed in man-rems) to all station personnel) as low as reasonably achievable.

The NRC staff believes that the stated objectives are attainable with current technology and with good operating practices. The costs for attaining these objectives have not been established and are expected to vary widely depending on the features of the specific power reactor facility and the method selected to accomplish the objectives. The favorable cost-benefit ratio for achieving some of these objectives may be obvious without a detailed study. For other objectives, however, a cost-benefit study might be required to determine whether the objectives are reasonably achievable. Doses to station personnel can affect station availability, and this factor should be considered in assessing the cost-benefit ratio.

Attaining the following objectives to the extent practicable, throughout the planning, designing, constructing, operating, and maintenance of an LWR station, will be considered to provide reasonable assurance that exposure levels of station personnel to radiation will be ALARA. The methods are deliberately stated such that considerable flexibility can be used in the manner by which the objectives can be achieved. Differences among stations might necessitate further innovation in methods used to achieve the objectives.

1. Program for Maintaining Station Personnel Radiation Doses ALARA

To attain the integrated effort needed to keep exposures of station personnel ALARA, each applicant and licensee should develop an ALARA Program that reflects the efforts to be taken by the utility, nuclear steam supply system vendor, and architect-engineer to maintain radiation exposure ALARA in all phases of a station's life. This ALARA Program should be in written form and should contain sections that cover the generally applicable guidance presented in this guide, as a minimum, and more specific guidance as required to address the particular LWR that is the subject of the licensing action. The ALARA Program may be combined with the station's Radiation Protection Manual, Safety Analysis Report, or other documents or submittals. It need not be an independent document.

a. Establishment of ALARA Program

(1) A management policy for, and commitment to, ensuring that the exposure of station personnel to radiation will be ALARA should be established.

(2) The policy and commitment should be reflected in written administrative procedures and instructions for operations involving potential exposures of personnel to radiation and should be reflected in station design features. Instructions to designers, constructors, vendors, and station personnel specifying or reviewing station features, systems, or equipment should reflect the ALARA goals and objectives. (Few utilities design or build their nuclear power stations; but as *customers* of designers and builders, utilities should expect the designers and builders to be responsive to their needs and instructions.)

b. Organization, Personnel, and Responsibilities

(1) In view of the need for upper-level management support, responsibility and authority for implementing the ALARA Program should be assigned to an individual with organizational freedom to ensure development and implementation. Responsibilities and authorities should include

(a) Ensuring that a corporate ALARA program that integrates management philosophy and regulatory requirements is established, with specific goals and objectives for implementation included;

(b) Ensuring that an effective measurement system is established and used to determine the degree of success achieved by station operations with regard to the ALARA goals and specific objectives;

(c) Ensuring that the measurement system results are reviewed on a periodic basis and that corrective actions are taken when attainment of the specific objectives appears to be jeopardized;

(d) Ensuring that the authority for providing procedures and practices by which the specific goals and objectives will be achieved is delegated; and

(e) Ensuring that the resources needed to achieve ALARA goals and objectives are made available.

In view of the responsibilities required to implement the ALARA Program, the individual (or committee) selected for this function might also be chosen to coordinate the effort among the several corporate functional groups (such as the operations, maintenance, technical support, engineering, safety, and radiation protection groups) and to represent the corporate interests in dealing with the NSSS designer, vendor, A/E, and builder during the design and construction phases. If the expertise for performing this function is not within the corporation when the station is in the design stage, consultants who possess the required expertise should be used. The utility should obtain assurance that available data and experience obtained from similar nuclear power stations are considered and reflected in the work of the NSSS designer, vendor, A/E, and builder so as to provide features in the new station that permit an effective ALARA Program.

(2) The Plant Manager (Superintendent, or equivalent) is responsible for all aspects of station operation, including the onsite radiation protection program.

Responsibilities of the Plant Manager with respect to the ALARA Program should include

(a) Ensuring support from all station personnel;
(b) Participating in the selection of specific goals and objectives for the station;
(c) Supporting the onsite Radiation Protection Manager (RPM) in formulating and implementing the station ALARA Program; and
(d) Expediting the collection and dissemination of data and information concerning the program to the corporate management.

(3) The Radiation Protection Manager (RPM) (onsite) has a safety-related function and responsibility to both employees and management that can be best fulfilled if the individual is independent of station divisions, such as operations, maintenance, or technical support, whose prime responsibility is continuity or improvement of station operability. The RPM should have direct recourse to responsible management personnel in order to resolve questions related to the conduct of the radiation protection program.

(The specific responsibilities given here for the RPM are illustrative and not intended to be all-inclusive with respect to the ALARA Program or effort. They do not include any of the responsibilities in areas other than ALARA efforts.)

Responsibilities of the RPM with respect to the ALARA Program should include

(a) Participating in design reviews for facilities and equipment that can affect potential radiation exposures;
(b) Identifying locations, operations, and conditions that have the potential for causing significant exposures to radiation;
(c) Initiating and implementing an exposure control program;
(d) Developing plans, procedures, and methods for keeping radiation exposures of station personnel ALARA;
(e) Reviewing, commenting on, and recommending changes in job procedures to maintain exposures ALARA;
(f) Developing and participating in training programs related to work in radiation areas or involving radioactive material;
(g) Supervising the radiation surveillance program to maintain data on exposures of and doses to station personnel, by specific job functions and type of work;
(h) Supervising the collection, analysis, and evaluation of data and information attained from radiological surveys and monitoring activities;[5]
(i) Supervising, training, and qualifying the radiation protection staff of the station; and
(j) Ensuring that adequate radiation protection coverage is provided for station personnel during all working hours.

Qualifications[6] needed for the RPM job as well as those needed for other positions in organizations operating nuclear power stations, are presented in Regulatory Guide 1.8, "Personnel Selection and Training."

c. Training and Instruction

A training program in the fundamentals of radiation protection and in station exposure control procedures should be established. It should include instructing all personnel whose duties require (1) working with radioactive materials, (2) entering radiation areas, or (3) directing the activities of others who work with radioactive materials or enter radiation areas. The training program also should include sufficient instruction in the biological effects of exposures to radiation to permit the individuals receiving the instruction to understand and evaluate the significance of radiation doses in terms of the potential risks.

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[5] Data collected during outages can indicate trends of radiation buildup in equipment that can permit estimates of probable radiation levels to be encountered during subsequent outages.

[6] Consideration has been given to peer group certification, i.e., certification of health physicists by the American Board of Health Physics (ABHP), as representing evidence of adequate qualifications for RPM candidates. While the staff believes that peer group certification is desirable, the present ABHP certification is not necessarily specifically applicable to applied health physics or radiation protection needs in nuclear power stations. However, the staff is discussing with the ABHP the prospects for a special certification program specifically directed toward the needs of radiation protection personnel at nuclear power stations.

The training should be commensurate with the duties and responsibilities of those receiving the instructions, as well as with the magnitude of the potential doses and dose rates that can be anticipated. Personnel (including contractor personnel) who direct the activities of others should be familiar with the licensee's radiation control program and should have the authority to implement the licensee's commitment to ensure that radiation exposures of station personnel will be ALARA.

The training program should include instruction on (1) radiation protection rules for the station and (2) the applicable federal regulations. Copies of these rules and regulations should be made available to those receiving the instructions. The training program should be approved by the RPM and presented by competent instructors under the RPM's supervision. The information presented in the training program should be reviewed periodically and modified, where necessary, to reflect contemporary techniques and adjustments based on experience in station operations. Instruction of station personnel should stress the importance of exposure-reduction efforts by every individual and should emphasize the need for feedback of information obtained when similar tasks were performed previously.

Station personnel should receive instruction at periodic intervals to reinforce their knowledge and keep it current. Station personnel whose duties do not require entering radiation areas or working with radioactive materials should receive sufficient instruction in radiation protection and station rules and regulations to understand why they should not enter such areas.

Training programs that have as their goal an increase in craft skills provide a broader base of knowledgeable station personnel available to service equipment in radiation areas and permit the services to be performed more reliably and more efficiently. This can promote lower individual and collective dose levels.

d. Review of New or Modified Designs and Equipment Selection

(1) Since several groups within a utility (for example, maintenance, operations, radiation protection, technical support, engineering, and safety groups) are interested in station design and equipment selection, the utility should ensure that these groups are adequately represented in the review of the design of the facility and the selection of equipment. A coordinated effort by the several functional groups within the utility is required to ensure that station features will permit the goals and objectives of the ALARA Program to be achieved. Although the A/E and designers greatly influence station design features, utilities should not delegate all responsibilities for station design review and equipment selection to the NSSS designer, vendor, or A/E.

(2) Design concepts and station features should reflect consideration of the activities of station personnel (such as maintenance, refueling, inservice inspections, processing of radioactive wastes, decontamination, and decommissioning) that might be anticipated and that might lead to personnel exposure to substantial sources of radiation. Station design features should be provided to reduce the anticipated exposures of station personnel to these sources of radiation to the extent practicable.

(3) Specifications for equipment should reflect the objectives of ALARA, including considerations of reliability, serviceability, limitations of internal accumulations of radioactive material, and other features addressed in this guide. Specifications for replacement equipment also should reflect modifications based on experience gained from using the original equipment.

2. Facility and Equipment Design Features

Radiation sources within a nuclear power station differ appreciably with respect to location, intensity, and characteristics. The magnitude of the dose rates that results from these sources is dependent on many factors, including the facility and equipment design, layout, mode and length of operation, and radiation source strength and characteristics.

To provide a basis for design, the quantity and isotopic composition of the radioactive material that can be anticipated to be contained, deposited, or accumulated in equipment during normal operation of the station should be estimated. Work on source term definition is being pursued by the ANSI N-237 working group. The method involves a mechanistic tracing of radioactive material from origin through treatment processes to release. It provides information that can be used as a starting point to estimate radiation sources within the station for normal operation.

Activation and neutron sources also should be identified and quantified. The nuclear steam system supplier can provide source data, which should be consistent with the design basis for the system (e.g., assuming 1% fuel cladding defects for operating conditions). Data obtained from measurements and experience in operating stations of similar design are most valuable as the basis for designing new stations. Extrapolation of data to equilibrium conditions may be needed to estimate ultimate source terms.

The magnitude of the dose is dependent on the length of time spent in the radiation field. ALARA Program objectives are presented below for each of several station features or functions. Each statement of objective is followed by a number of specific concerns or suggestions that should be addressed.

a. Access Control of Radiation Areas

To avoid unnecessary and inadvertent exposures of personnel to radiation, the magnitude of the potential dose rates at all locations within the station should be estimated during station design. Actual dose rates should be measured periodically during operation to determine current exposure potentials. Zones associated with the higher dose rates should be kept as small as reasonably achievable consistent with accessibility for accomplishing the services that must be performed in those zones, including equipment laydown requirements. Radiation zones where station personnel spend substantial time should be designed to the lowest practicable dose rates.

(It is common practice to identify "radiation zones" within a nuclear power station. The zone designations are established to reflect the design maximum dose rates that may exist in areas within the station where station personnel must have access to perform required services. Several systems for designating "radiation zones" currently exist among the utilities, and ANSI Committee 6.7 is developing a standard that should prove useful in attaining common designations and terminology in this matter. To avoid ambiguity, no reference to radiation zone numbers is used in this guide at this time.)

A system should be established to permit effective control over personnel access to the radiation areas and control over the movement of sources of radiation within the station. Where high radiation areas (>100 mrem/hr) exist, 10 CFR Part 20, § 20.203 requires that station design features and administrative controls provide effective ingress control, ease of egress, and appropriate warning devices and notices. Access control of radiation areas also should reflect the following considerations:

(1) Extraordinary design features are warranted to avoid any potential dose to personnel that is large enough to cause acute biological effects and that could be received in a short period of time. Positive control of ingress to such areas, permanent shielding, source removal, or combinations of these alternatives can reduce the dose potential.

(2) Administrative controls such as standard operating procedures can be effective in preventing inadvertent exposures of personnel and the spread of contamination when radioactive material or contaminated equipment must be transported from one station location to another and when the route of transport through lower radiation zones or "clean" areas cannot be avoided.

(3) Station features such as platforms or walkways, stairs, or ladders that permit prompt accessibility for servicing or inspection of components located in higher radiation zones can reduce exposure of personnel who must perform these services.

b. Radiation Shields and Geometry

Radiation shields should be designed using conservative assumptions for radioactive source quantities and geometries. Calculational methods selected to determine shield thicknesses should be known to provide reliable and accurate results. Shield design features should reflect the following ALARA considerations:

(1) Exposure of personnel servicing a specific component (such as a pump, filter, or valve) to radiation from other components containing radioactive material can be reduced by providing shielding between the individual components that constitute substantial radiation sources and the receptor.

(2) Where it is impracticable to provide permanent shielding for individual components that constitute substantial radiation sources, the exposure of personnel maintaining such components can be reduced (a) by providing as much distance as practicable between the serviceable components and the substantial radiation sources in the area and (b) by providing temporary shields around components that contribute substantially to the dose rate.

(3) Potential exposure of station personnel to radiation from certain systems containing radiation sources can be reduced by means of a station layout that permits the use of distance and shielding between the sources and work locations. These systems include (but are not limited to) the NSSS and the reactor water cleanup, offgas treatment, solid waste treatment, and storage systems, as well as systems infrequently containing radiation sources, such as the standby gas treatment and residual heat removal systems.

Radiation from an operating BWR turbine can constitute a substantial source of exposure for construction personnel or others who have access to the site for extended periods of time if insufficient shielding is provided.

(4) Streaming or scattering of radiation from locally shielded components (such as cubicles) can be reduced by providing labyrinths for access. However, such labyrinths or other design features of the cubicle should permit the components to be removed readily from the cubicle for repair or replacement. Single-scatter labyrinths may be inadequate if the cubicle contains a substantial radiation source.

(5) Streaming of radiation into accessible areas through penetrations for pipes, ducts, and other shield discontinuities can be reduced (a) by means of layouts that prevent substantial radiation sources within the shield from being aligned with the penetrations or (b) by using "shadow" shields such as shields of limited size that attenuate the direct radiation component. Streaming also can occur through roofs or floors unless adequate shielding encloses the source from all directions.

(6) The exposure of station personnel to radiation from pipes carrying radioactive material can be reduced by means of shielded chases.

(7) Design features that permit the rapid removal and reassembly of shielding, insulation, and other material from equipment that must be inspected or serviced periodically can reduce the exposure of station personnel performing these activities.

(8) Space within cubicles and other shielding to provide laydown space for special tools and ease of servicing activities can reduce potential doses by permitting the services to be accomplished expeditiously, thus reducing exposure time.

(9) The exposure of personnel who service components that constitute substantial radiation sources or are located in high radiation fields can be minimized by removing the components and transporting them to low radiation zones where shielding and special tools are available. Design features that permit the prompt removal and installation of these components can reduce the exposure time.

(10) Floor and equipment drains, piping, and sumps that are provided to collect and route any contaminated liquids that might leak or be spilled from process equipment or sampling stations can become substantial radiation sources. The drain lines can be located in concrete floors, concrete ducts, columns, or radwaste pipe chases to provide shielding. These systems can also become a source of airborne contamination because of the potential for gases to form in, and be released by, such systems (see Section C.2.d.(6)).

c. Process Instrumentation and Controls

Appropriate station layout and design features should be provided to reduce the potential doses to personnel who must operate, service, or inspect station instrumentation and controls. The following considerations should be reflected in selecting the station features.

(1) The exposure of personnel who must manually operate valves or controls can be reduced through the use of "reach rods" or remotely operated valves or controls. However, these devices can require lubrication and maintenance that can be the source of additional exposures, and these factors should be taken into consideration.

(2) The exposure of personnel who must view or operate instrumentation, monitors, and controls can be reduced by locating the readouts or control points in low radiation zones.

(3) Instrumentation must satisfy functional requirements, but the exposure of personnel can be reduced if the instruments are designed, selected, specified, and located with consideration for long service-life, ease and low frequency of maintenance and calibration, and low crud accumulation. Operating experience should be recorded, evaluated, and reflected in the selection of replacement instrumentation.

(4) The use of instrumentation that contains minimal quantities of contaminated working fluid, (for example, pressure transducers rather than bellows-type pressure gauges) can reduce the potential for exposure at the readout locations.

d. Control of Airborne Contaminants and Gaseous Radiation Sources

Station design features should be provided in all station work areas to limit the average concentrations of radioactive material in air to levels well below the values listed in Appendix B, Table 1, Column 1 of 10 CFR Part 20. Effective design features can minimize the occurrence of occasional increases in air contamination and the concentrations and amounts of contaminants associated with any such occasional increases. Designs that permit repeated, identified releases of large amounts of radioactive materials into the air spaces occupied by personnel are contrary to an ALARA program.

Station design features should provide for protection against airborne radioactive material by means of engineering controls such as process, containment, and ventilation equipment. The routine provision of respiratory protection by use of individually worn respirators rather than engineered design features is generally unacceptable. The use of respirators, however, might be appropriate in certain nonroutine or emergency operations when the application of engineering controls is not feasible or while such controls are being installed.

The approved use of respirators is subject to the requirements of 10 CFR Part 20, § 20.103, "Exposure of Individuals to Concentrations of Radioactive Materials in Air in Restricted Areas," and to regulatory guidance on acceptable use. (See Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," and NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials" (Ref. 6).) Design features of the station ventilation system and gaseous radwaste processing systems should reflect the following considerations:

(1) The spread of airborne contamination within the station can be limited by maintaining air pressure gradients and air flows from areas of low potential airborne contamination to areas of higher potential contamination. Periodic checks would ensure that the design pressure differentials are being maintained.

(2) Effectively designed ventilation systems and gaseous radwaste treatment systems will contain radioactive material that has been deposited, collected, stored, or transported within or by the systems. Exposures of station personnel to radiation and to contamination from ventilation or gaseous radwaste treatment components occur as a result of the need to service, test, inspect, decontaminate, and replace components of the systems or perform other duties near these systems. Potential doses from these systems can be minimized by providing ready access to the systems, by providing space to permit the activities to be accomplished expeditiously, by separating filter banks and components to reduce exposures to radiation from adjacent banks and components, and by providing sufficient space to accommodate auxiliary ventilation or shielding of components.

(3) Auxiliary ventilation systems that augment the permanent system can provide local control of airborne contaminants when equipment containing potential airborne sources is opened to the atmosphere. Two types of auxiliary ventilation systems have proven to be effective. In areas where contaminated equipment must be opened frequently, dampers and fittings can be provided in ventilation ducts to permit the attachment of flexible tubing or "elephant trunks" without imbalancing the ventilation system. In areas where contaminated equipment must be opened infrequently, portable auxiliary ventilation systems featuring blowers, HEPA filters, and activated charcoal filters (where radioiodine might be anticipated) on carts can be used effectively. Portable auxiliary ventilation systems should be tested frequently to verify the efficiency of the filter elements in their mountings. When the efficiency has been verified, the system may be exhausted to the room or the ventilation exhaust duct without further treatment and thus imbalance of the permanent ventilation system can be avoided.

(4) Machining of contaminated surfaces (e.g., welding, grinding, sanding, or scaling) or "plugging" of leaking steam generator or condenser tubes can be substantial sources of airborne contamination. These sources can be controlled by using auxiliary ventilation systems.

(5) Sampling stations for primary coolant or other fluids containing high levels of radioactive material can constitute substantial sources of airborne contamination. Such sources can be controlled by using auxiliary ventilation systems.

(6) Wet transfer or storage of potentially contaminated components will minimize air contamination. This can be accomplished by keeping contaminated surfaces wet, by spraying, or, preferably, by keeping such surfaces under water.

e. Crud Control

Design features of the primary coolant system, the selection of construction materials that will be in contact with the primary coolant, and features of equipment that treat primary coolant should reflect considerations that will reduce the production and accumulation of crud in stations where it can cause high exposure levels. The following items should be considered in the crud control effort.

(1) Production of Co-58 and Co-60, which constitute substantial radiation sources in crud, can be reduced by specifying, to the extent practicable, low nickel and low cobalt bearing materials for primary coolant pipe, tubing, vessel internal surfaces, heat exchangers, wear materials, and other components that are in contact with primary coolant. Colmonoys and Hastelloys can frequently be substituted for stellite for hard facings of wear material, and Alloy-800 can frequently be substituted for Alloy-600 in heat exchangers.

(2) Loss of material by erosion of load-bearing hard facings can be reduced by using favorable geometrics and lubricants, where practicable, and by using controlled leakage purge across journal sleeves to avoid entry of particles into the primary coolant.

(3) Loss of material by corrosion can be reduced by continuously monitoring and adjusting oxygen concentration and pH in primary coolant above 250°F and by using bright hydrogen-annealed tubing

and piping in the primary coolant and feedwater systems.

(4) Crud can be removed from primary coolant by high-temperature filtration (graphite or magnetic filters), by reactor water cleanup systems, by isolation and chemical decontamination of major serviceable components of the system, and by draining and flushing of the system.

(5) Leakage of contaminated coolant from the primary system can be reduced by using live-loaded valve packings and bellow seals.

(6) Deposition of crud within the primary coolant system can be reduced by providing laminar flow and smooth surfaces for coolant and by minimizing crud traps in the system to the extent practicable.

f. Isolation and Decontamination

Potential doses to station personnel who must service equipment containing radioactive sources can be reduced by removing such sources from the equipment (decontamination), to the extent practicable, prior to servicing. Serviceable systems and components that constitute a substantial radiation source should be designed, to the extent practicable, with features that permit isolation and decontamination. Station design features should consider, to the extent practicable, the ultimate decommissioning of the facility and the following concerns:

(1) The necessity for decontamination can be reduced by limiting, to the extent practicable, the deposition of radioactive material within the processing equipment—particularly in the "dead spaces" or "traps" in components where substantial accumulations can occur. The deposition of radioactive material in piping can be reduced and decontamination efforts enhanced by avoiding stagnant legs, by locating connections above the pipe centerline, by using sloping rather than horizontal runs, and by providing drains at low points in the system.

(2) The need to decontaminate equipment and station areas can be reduced by taking measures that will reduce the probability of release, reduce the amount released, and reduce the spread of the contaminant from the source (e.g., from systems or components that must be opened for service or replacement). Such measures can include auxiliary ventilation systems (see C.4.b), treatment of the exhaust from vents and overflows (see C.2.h.(8)), drainage control such as curbing and floors sloping to local drains, or sumps to limit the spread of contamination from leakage of liquid systems.

(3) Accumulations of crud or other radioactive material that cannot be avoided within components or systems can be reduced by providing features that will permit the recirculation or flushing of fluids with the capacity to remove the radioactive material through chemical or physical action. The fluids containing the contaminants will require treatment, and this source should be considered in sizing station radwaste treatment systems.

(4) Continuity in the functioning of processing or ventilation systems that are important for controlling potential doses to station personnel can be provided during servicing of the systems if redundant components or systems are available so that the component (with associated piping) being serviced can be isolated.

(5) The potential for contamination of "clean services" (such as station service air, nitrogen, or water supply) from leakage from adjacent systems containing contaminants can be reduced by separating piping for these services from piping that contains radioactive sources. Piping that carries radioactive sources can be designed for the lifetime of the station, thus avoiding the necessity for replacement (and attendant exposures) and lessening the potential for contamination of clean services if it is impracticable to provide isolation through separate chases.

(6) Surfaces can be decontaminated more expeditiously if they are smooth, nonporous, and free of cracks, crevices, and sharp corners. These desirable features can be realized by specifying appropriate design instructions, by giving attention to finishing work during construction or manufacture, and by using sealers (such as special paints) on surfaces where contamination can be anticipated. (ANSI N-101.2 provides helpful guidance on this matter (Ref. 7).)

(7) Where successful decontamination of important systems could be prevented by an anticipated failure of a critical component or feature, additional features that permit alternative decontamination actions can be provided.

(8) Contaminated water and deposited residues in spent fuel storage pools contribute to the exposure at accessible locations in the area. Treatment systems that remove contaminants from the water can perform more efficiently (a) if intake and discharge points for the treatment systems are located to provide enhanced mixing and to avoid stagnation areas in the pool and (b) if pool water overflows and skimmer tanks are provided. Fluid jet or vacuum cleaner type agitators can help reduce the settling of crud on surfaces of the pool system.

g. Radiation Monitoring Systems

Central or "built-in" monitoring systems that give information on the dose rate and concentration of airborne radioactive material in selected station areas can reduce the exposure of station personnel who would be required to enter the areas to obtain the data if such systems were not provided. These systems also can provide timely information regarding changes in the dose rate or concentrations of airborne radioactive material in the areas. (The installation of a central monitoring system is easier and less expensive if it is a part of the original station design.) The selection or design and installation of a central monitoring system should include consideration of the following desirable features:

(1) Readout capability at the main radiation protection access control point;
(2) Placement of detectors for optimum coverage of areas;
(3) Circuitry that indicates component failure;
(4) Local alarm and readout;
(5) Clear and unambiguous readout;
(6) Ranges adequate to ensure readout of the highest anticipated radiation levels and to ensure positive readout at the lowest anticipated levels; and
(7) Capability to record the readout of all systems.

h. Resin and Sludge Treatment Systems

Systems used to transport, store, or process resins or slurries of filter sludge present a special hazard because of the concentrated nature of the radioactive material. Design features for resin and sludge-handling systems should reflect this concern and the following specific considerations:

(1) The accumulation of radioactive material in components of systems used to process resin and sludges can be reduced by

(a) Reducing the length of piping runs;
(b) Using larger diameter piping;
(c) Reducing the number of pipe fittings;
(d) Avoiding low points and dead legs in piping;
(e) Using gravitational flow to the extent practicable; and
(f) Minimizing flow restrictions of processed material.

(2) The need for maintenance and the presence of intense local radiation sources can be reduced by

(a) Using full ported valves constructed such that the slurry will not interfere with the opening or closing of the valve and
(b) Avoiding cavities in valves.

(3) The deposition of resin and sludge that would occur if elbow fittings were used can be reduced by using pipe bends of at least five pipe diameters in radius. Where pipe bends cannot be used, long radius elbows are preferred.

(4) Smoother interior pipe surfaces at connections (with attendant reductions in friction losses, deposition of material, and tendencies to "plug") can be achieved by using butt welds rather than socket welds and by using consumable inserts rather than backing rings.

(5) Where the use of tees cannot be avoided, line losses can be reduced if the flow is through the run (straight section) of the tee, and accumulations of material in the branch of the tee can be reduced by orienting the branch horizontally or (preferably) above the run.

(6) Slurry piping is subject to plugging that may require backflushing from the tank and equipment isolation valves and pressurizing with water, nitrogen, or air to "blow out" plugged lines. However, the use of pressurized gas for blowing out lines can present a potential contamination source and may not be effective in relieving plugged lines.

(7) Water, air, or nitrogen for sparging can be used to fluidize resins or sludges in storage tanks. The use of gases, however, presents a potential source of airborne contamination and tank rupture from overpressures.

(8) The spread of contamination by the loss of resin or sludge through overflows and vents can be reduced by using screens, filters, or other features that will collect and retain solids. However, such features generally require cleaning by remote flushing, by rapid replacement, or by other means to reduce exposures during servicing.

i. Other Features

Station layout and station tasks should be reviewed to identify and provide special features that complement the ALARA Program. Station design should reflect consideration of the following concerns:

(1) The selection of radiation-damage-resistant materials for use in high radiation areas can reduce the need for frequent replacement and can reduce the probability of contamination from leakage.

(2) The use of stainless steel for constructing or lining components, where it is compatible with the process, can reduce corrosion and can provide options for decontamination methods.

(3) Field-run piping that carries radioactive material can cause unnecessary exposures unless due consideration is given to the routing. Such unnecessary exposures can be avoided if the routing is accomplished under the cognizance of an engineer

familiar with the principles of radiation protection or if a detailed piping layout is provided, i.e., if the piping is not field-run.

(4) Where filters or other serviceable components can constitute substantial radiation sources, exposures can be reduced by providing features that permit operators to avoid the direct radiation beam and that provide remote removal, installation, or servicing. Standardization of filters should be considered.

(5) The servicing of valves can be a substantial source of doses to station personnel. These doses can be reduced by providing adequate working space for easy accessibility and by locating the valves in areas that are not in high radiation fields.

(6) Potential doses from servicing valves and from leakage can be reduced by specifying and installing the "best available" valves for the required service, by using radiation-damage-resistant seals and gaskets, and by using valve back seats. The use of straight-through valve configurations can avoid the buildup of accumulations in internal crevices and the discontinuities that exist in valves of other configurations. In most cases, valves can be installed in the "stem-up" orientation to facilitate maintenance and to minimize crud traps.

(7) Leaks from pumps can be reduced by using canned pumps where they are compatible with the service needs. If mechanical seals are used on a pump in a slurry service, features that permit the use of flush water to clean pump seals can reduce the accumulation of radioactive material in the seals. Drains on pump housings can reduce the radiation field from this source during servicing. Provision for the collection of such leakage or disposal to a drain sump is appropriate.

(8) The sources of radiation such as sedimentation that occurs in tanks used to process liquids containing radioactive material and residual liquids can be reduced when servicing by draining the tanks. The design can include sloping the tank bottoms toward outlets leading to other reprocessing equipment and, where practicable, providing built-in spray or surge features.

(9) Spare connections on tanks or other components located in higher radiation zones may be desirable to provide flexibility in operations. Exposures of personnel can be avoided if these connections are provided as a part of the original equipment rather than by subsequent modification of the equipment in the presence of radiation.

(10) Inspections to satisfy the ASME Code (Ref. 8) and regulatory requirements can result in exposures of station personnel to radiation. Many of the objectives presented above will aid in reducing potential exposures to personnel who perform the required inspections. Station features and design should, to the extent practicable, permit inspections to be accomplished expeditiously and with minimal exposure of personnel. The ALARA effort can also be aided by prompt accessibility, shielding and insulation that can be quickly removed and reinstalled, and special tools and instruments that reduce exposure time or permit remote inspection of components or equipment containing potential radiation sources.

(11) Components can be removed from processing systems more expeditiously if adequate space is provided in the layout of the system and if the interconnections permit prompt disconnects.

(12) Station features that provide a favorable working environment, such as adequate lighting, ventilation, working space, and accessibility (via such means as working platforms, cat walks, and fixed ladders), can promote work efficiency.

(13) The exposure of station personnel who must replace lamps in high radiation areas can be reduced by using extended service lamps and by providing design features that permit the servicing of the lamps from lower radiation areas.

(14) An adequate emergency lighting system can reduce potential exposures of station personnel by permitting prompt egress from high radiation areas if the station lighting system fails.

3. Radiation Protection Program

A substantial portion of the radiation dose to station personnel is received while they are performing services such as maintenance, refueling, and inspection in high radiation areas. The objectives that were presented in Section C.2 can provide station design features conducive to an effective ALARA Program. However, an effective ALARA Program also requires station operational considerations in terms of procedures, job planning, record keeping, special equipment, operating philosophy, and other support. This section deals with the manner in which the station administrative efforts can influence the variables of (1) the number of persons who must enter high radiation areas or contaminated areas, (2) the period of time the persons must remain in these areas, and (3) the magnitude of the potential dose.

a. Preparation and Planning

Before entering radiation areas where significant doses could be received, station personnel should have the benefit of preparations and plans that can ensure that exposures are ALARA while the personnel are performing the services. Preparations and plans should reflect the following considerations:

(1) A staff member who is a specialist in radiation protection can be assigned the responsibility for contributing to and coordinating ALARA efforts in support of operations that could result in substantial individual and collective dose levels.

(2) To provide the bases for planning the activity, surveys can be performed to ascertain information with respect to radiation, contamination, airborne radioactive material, and mechanical difficulties that might be encountered while performing services.

(3) Radiation surveys provided in conjunction with inspections or other activities can define the nature of the radiation fields and identify favorable locations where personnel may take advantage of available shielding, distance, geometry, and other factors that affect the magnitude of the dose rate or the portions of the body exposed to the radiation.

(4) Photographs of "as installed" equipment or components can be valuable for planning purposes and can be augmented by additional photos taken during the surveys. The use of portable TV cameras with taping features has considerable merit as both an operational aid and a teaching aid.

(5) The existing radiation levels frequently can be reduced by draining, flushing, or other decontamination methods or by removing and transporting the component to a lower radiation zone. An estimate of the potential doses to station personnel expected to result from these procedures is germane in selecting among alternative actions.

(6) A pre-operational briefing for personnel who will perform services in a high radiation area can ensure that service personnel understand the tasks about to be performed, the information to be disseminated, and the special instructions to be presented.

(7) A program can be implemented to provide access control and to limit exposures to those persons needed to perform the required services in the radiation areas. Such a program would address conditions that require a special work permit or other special procedures.

(8) A work permit form with an appropriate format can be useful for recording pertinent information concerning tasks to be performed in high radiation areas so that the information is amenable to cross-referencing and statistical analysis. Information of interest would include the following items:

(a) Designation of services to be performed on specific components, equipment, or systems;
(b) Number and identification of personnel working on the tasks;
(c) Anticipated radiation, airborne radioactive material, and contamination levels, based on current surveys of the work areas, and date of survey;
(d) Monitoring requirements, such as continuous air monitoring or sampling equipment;
(e) Estimated exposure time required to complete the tasks and the estimated doses anticipated from the exposure;
(f) Special instructions and equipment to minimize the exposures of personnel to radiation and contamination;
(g) Protective clothing and equipment requirements;
(h) Personnel dosimetry requirements;
(i) Authorization to perform the tasks; and
(j) Actual exposure time, doses, and other information obtained during the operation.

(9) Consideration of potential accident situations or unusual occurrences (such as gross contamination leakage, pressure surges, fires, cuts, punctures, or wounds) and contingency planning can reduce the potential for such occurrences and enhance the capability for coping with the situations expeditiously if they occur.

(10) Portable or temporary shielding can reduce dose rate levels near "hot spots" and in the general area where the work is to be performed.

(11) Portable or temporary ventilation systems or contamination enclosures and expendable floor coverings can control the spread of contamination and limit the intake by workers through inhalation.

(12) "Dry runs" on mock-up equipment can be useful for training personnel, identifying problems that can be encountered in the actual task situation, and selecting and qualifying special tools and procedures to reduce potential exposures of station personnel.

(13) Adequate auxiliary lighting and a comfortable environment (for example, vortex tube coolers for supplied air suits) can increase the efficiency of the work and thus reduce the time spent in the higher radiation zones.

(14) Radiation monitoring instruments selected and made available in adequate quantities can permit accurate measurements and rapid evaluations of the radiation and contamination levels and changes in levels when they occur. Routine calibration of instruments with appropriate sources and testing can ensure operability and accuracy of measurements.

(15) Performing work on some components inside disposable tents or, for less complicated jobs, inside commercially available disposable clear plastic glove bags can limit the spread of contamination. Such measures can also avoid unnecessary doses

resulting from the need to decontaminate areas to permit personnel access or to allow for entry with less restrictive protective clothing and equipment requirements.

(16) Careful scheduling of inspections and other tasks in high radiation areas can reduce exposures by permitting decay of radiation sources during the reactor shutdown period and by eliminating some repetitive surveys. Data from surveys and experience attained in previous operations and current survey data can be factored into the scheduling of specific tasks.

b. Operations

During operations in radiation areas, adequate supervision and radiation protection surveillance should be provided to ensure that the appropriate procedures are followed, that planned precautions are observed, and that all potential radiation hazards that might develop or that might be recognized during the operation are addressed in a timely and appropriate manner.

(1) Assigning a health physics (i.e., radiation safety or radiation protection) technician the responsibility for providing radiation protection surveillance for each shift operating crew can help ensure adequate radiation protection surveillance.

(2) Personnel monitoring equipment such as direct-reading dosimeters, alarming dosimeters, and personal dose rate meters can be used to provide early evaluation of doses to individuals and the assignment of those doses to specific operations (see Regulatory Guides 1.16, "Reporting of Operating Information—Appendix A Technical Specifications," and 8.4, "Direct-Reading and Indirect-Reading Pocket Dosimeters").

(3) Communication systems between personnel in high radiation zones and personnel who are monitoring the operation in other locations can permit timely exchanges of information and avoid unnecessary exposures to monitoring personnel.

c. Postoperations

Observations, experience, and data obtained during nonroutine operations in high radiation zones should be ascertained, recorded, and analyzed to identify deficiencies in the program and to provide the bases for revising procedures, modifying features, or making other adjustments that may reduce exposures during subsequent similar operations.

(1) Formal or informal postoperation debriefings of station personnel performing the services can provide valuable information concerning shortcomings in pre-operational briefings, planning, procedures, special tools, and other factors that contributed to the cause of doses received during the operation.

(2) Dose data obtained during or subsequent to an operation can be recorded in a preselected manner as part of a "Radiation Work Permit" or similar program [see C.3.a(8)] so that the data are amenable to statistical analyses.

(3) Information concerning the cause of component failures that resulted in the need for servicing in high radiation areas can provide a basis for revising specifications on replacement equipment or for other modifications that can improve the component reliability. Such improvements can reduce the frequency of servicing and thus reduce attendant exposures.

(4) Information gained in operations can provide a basis for modifying equipment selection and design features of new facilities.

(5) Summaries of doses received by each category of maintenance activity can be reviewed periodically by upper management to compare the incremental reduction of doses with the cost of station modifications that could be made.

4. Radiation Protection Facilities, Instrumentation, and Equipment

A radiation protection staff with facilities, instrumentation, and protective equipment adequate to permit the staff to function efficiently is an important element in achieving an effective ALARA program. The selection of instrumentation and other equipment and the quantities of such equipment provided for normal station operations should be adequate to meet the anticipated needs of the station during normal operations and during major outages that may require supplemental workers and extensive work in high radiation areas. (Accident situations are not considered in this guide.) Station design features and provisions should reflect the following considerations.

a. Counting Room

A low-radiation background counting room is needed to perform routine analyses on station samples containing radioactive material collected from air, water, surfaces, and other sources. An adequately equipped counting room would include

(1) Multichannel gamma pulse height analyzer (Regulatory Guide 5.9, "Specifications for Ge(Li) Spectroscopy Systems for Material Protection Measurements—Part 1: Data Acquisition Systems," provides guidance for selecting Ge(Li) spectroscopy systems);

(2) Low-background alpha-beta radiation proportional counter(s) or scintillation counter(s);

(3) End-window Geiger-Muller (G-M) counter(s); and

(4) A liquid scintillation counter for tritium analyses. Analyses of bioassay and environmental samples and whole body counting (see Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program") call for additional equipment and laboratory space if the analyses are performed by station personnel rather than by other specialists through contractual arrangements.

b. Portable Instruments

Portable instruments needed for measuring dose rates and radiation characteristics would include

(1) Low-range (nominally 0 to 5 R per hour) ion chambers or G-M rate meters;
(2) High-range (0.1 to at least 500 R per hour) ion chambers;[7]
(3) Alpha scintillation or proportional count rate meters;
(4) Neutron dose equivalent rate meters;
(5) Air samplers for short-term use with particulate filters and iodine collection devices (such as activated charcoal cartridges); and
(6) Air monitors with continuous readout features.[7]

c. Personnel Monitoring Instrumentation

Personnel monitoring instrumentation selection should include consideration of

(1) G-M "Friskers" for detecting low levels of radioactive material;
(2) Direct-reading low-range (0 to 200 mR) and intermediate-range (0 to 1000 mR) pocket dosimeters (see Regulatory Guide 8.4);
(3) Alarm dosimeters;
(4) Film badges and/or thermoluminescent dosimeters (TLD);
(5) Hand and foot monitors; and
(6) Portal monitors.

d. Protective Equipment

Utility-supplied protective equipment selection should include consideration of

(1) Anti-contamination clothing and equipment that meet the requirements of ANSI Z-88.2, 1969, for use in atmospheres containing radioactive materials, or the National Institute of Occupational Safety and Health's (NIOSH) "Certified Personal Protective Equipment List," July 1974, and current supplements from DHEW/PHS (Refs. 9 and 10).

(2) Respiratory protective equipment including a respirator fitting program that satisfies the guidance of Regulatory Guide 8.15 and NUREG-0041 (Ref. 6).

e. Support Facilities

Design features of radiation protection support facilities should include consideration of

(1) A portable-instrument calibration area designed and located such that radiation in the calibration area will not interfere with low level monitoring or counting systems;

(2) Personnel decontamination area (this facility should be located and designed to expedite rapid cleanup of personnel and should not be used as a multiple-purpose area or share ventilation with food-handling areas) with showers, basins, and installed "frisker" equipment;

(3) Facilities and equipment to clean, repair, and decontaminate personnel protective equipment, monitoring instruments, hand tools, electromechanical parts, or other material (highly contaminated tools or other equipment should not be decontaminated in the area used to clean respiratory equipment);

(4) Change rooms that (preferably) connect with the personnel decontamination area and a control station area equipped with sufficient lockers to accommodate permanent and contract maintenance workers who may be required during major outages;

(5) Control stations for entrance or exit of personnel into radiation and contamination controlled access areas of the station, such as the personnel entrance to the containment buildings and the main entrance to the radwaste processing areas; these control stations also may be used as the control point for radioactive material movements throughout the station and for the storage of portable radiation survey equipment, signs, ropes, and respiratory protective equipment;

(6) Equipment to facilitate communication between all areas throughout the stations; and

(7) Sufficient office space to accommodate the temporary and permanent radiation protection staff, permanent records, and technical literature.

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[7] Variable alarm set point features on these instruments can be valuable in providing a warning when unexpected substantial changes in dose rate or air concentration occur.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

This guide reflects current NRC staff practice in license application reviews. Therefore, except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described herein are being and will continue to be used in the evaluation of submittals for construction permits and operating license applications until this guide is revised as a result of suggestions from the public or additional staff review.

At the operating license review stage, the radiation protection design presented in the applicant's final safety analysis report will be reviewed against Section C.2 of this guide and differences from the recommendations of the guide will be identified (particularly for plants designed before Regulatory Guide 8.8 was issued). However, no substantive design changes will be required at the operating license stage unless the design change can prevent substantial man-rem exposures which cannot be prevented by procedural measures and the design change is consistent with the cost-effectiveness principle of the ALARA philosophy.

Methods other than those set forth in this guide may be substituted for those stated herein, provided they satisfy the criterion "as low as is reasonably achievable" of 10 CFR Part 20, §20.1(c).

REFERENCES

1. Ad Hoc Committee of the National Council on Radiation Protection and Measurements, "Somatic Radiation Dose for the General Population," Science 131, 482 (1960).

2. "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," National Academy of Sciences/National Research Council, DHEW Contract PH-43-64-44, November 1972.

3. C. A. Pelletier et al., "Compilation and Analysis of Data on Occupational Radiation Exposure Experienced at Operating Nuclear Power Plants," Atomic Industrial Forum, 1974.

4. T. D. Murphy, N. J. Dayem, J. Stewart Bland, and W. J. Pasciak, "Occupational Radiation Exposure at Light-Water-Cooled Power Reactors, 1969-1975," NUREG-0109, U.S. Nuclear Regulatory Commission, August 1976. Copies may be obtained from the National Technical Information Service, Springfield, Va. 22161.

5. Proceedings, Public Meeting on Revision of Regulatory Guide 8.8, "Information Relevant to Assuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable," April 25, 1975, p. 171, available in the NRC Public Document Room.

6. Copies of NUREG-0041 may be obtained from the National Technical Information Service, Springfield, Va. 22161.

7. ANSI N-101.2, "Protective Coatings (Paints) for Light Water Nuclear Reactor Containment Facilities." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, N.Y. 10018.

8. Section XI, ASME Boiler and Pressure Vessel Code and Addenda. Copies may be obtained from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, N.Y. 10017.

9. ANSI Z-88.2, "Practices for Respiratory Protection." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, N.Y. 10018.

10. NIOSH, "Certified Personal Protective Equipment List," July 1974, and supplements by DHEW/PHS. Published by U.S. Department of Health, Education and Welfare, Public Health Service, Center of Disease Control, National Institute of Occupational Safety and Health. Copies are available from the Office of Technical Publications, National Institute of Occupational Safety and Health, Post Office Building, Cincinnati, Ohio 45202.

[The following information was subsequently received for the record:]

U.S. Nuclear Regulatory Commission,
Washington, D.C., October 3, 1977.

Hon. Warren G. Magnuson,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Mr. Chairman: In response to your recent letter, I am pleased to submit answers to the additional questions you forwarded in connection with Committee hearings on radiation health and safety. If I can provide any further information, please let me know.

Sincerely,

Lee V. Gossick,
Executive Director for Operations.

Enclosures.

Question 1. Please submit to the Committee copies of the following materials:[1]

(a) The report of the NRC task force, established to study the need to regulate the use of naturally-occurriing radioactive materials and accelerator-produced radioactive materials.

Answer. Enclosed is a copy of the NARM Task Force Report, published as NUREG–0301, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials."

(b) The proposed agenda of the task force established to review the adequacy of the Rasmussen Report and a list of task force members.

Answer. Enclosed is a copy of the Federal Register notice of July 7, 1977, (42 FR 34955) announcing the establishment of the Risk Assessment Review Group, and a list of the members of the Review Group.

(c) The environmental impact statement which reviewed the health and environmental effects of non-ionizing radiation emitted from high-powered transmission lines.

Answer. Enclosed is an NRC document, NUREG–0316, "Alternative Electric Transmission Systems and Their Environmental Impact." Also enclosed is an EPA report, EPA–520/2–76–008, "An Examination of Electric Fields Under EHV Overhead Power Transmission Lines."

(d) The report, compiled at the request of the GAO and Congressman Dingall's Subcommittee on Energy and Power, concerning the loss of strategic nuclear material from NRC regulated facilities.

Answer. A copy of the report discussing and listening inventory differences of special nuclear material, NUREG–0350, "Report on Strategic Special Nuclear Material Inventory Differences," is enclosed.

(e) The report on the exposure of workers at the Apollo plant to high levels of gaseous effluents.

Answer. The identity of this report is not clear in the transcript. We assume this refers to requested material on p. 387. Accordingly, the following has been taken from NRC records which are available in the Public Document Room:

SNM 145—NUMEC

Individual exposed to airborne radioactive material exceeding limits for a seven consecutive day period:

EXPOSURE HOUR RANGE AT MPC[1]

Year	40 to 70	71 to 150	More than 150[2]
Number of individuals:			
1974	7	4	6
1975	6	5	0
1976	6	0	0
1977	0	0	0

[1] Maximum permissible concentration for 7 consecutive days.
[2] Ranges from 247 to 1,239 MPC hours (see attached exposure reports).

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[1] The materials have been placed in the committee files.

Question 2. During the hearing, you cited three areas where improvements in the nucelar regulatory process are needed, including clearer definitions of limits of authority among agencies.

(a) The Committee would welcome your suggestions for revising statutory definitions.

Answer. The need for better delineation of authority between agencies having statutory authority for radiation protection has increased considerably since we presented our testimony. The recent 1977 amendments to the Clean Air Act which were enacted subsequent to our testimony have intensified this need. These amendments provide a mechanism for regulatory control under the Clean Air Act of airborne radioactive emissions including materials licensed by the NRC under the Atomic Energy Act of 1954, as amended. The amendments result in duplicative authority shared between NRC, EPA, and the States for regulation of airborne emissions of source materials, byproduct materials, and special nuclear materials.

As stated in our testimony, we support the roles of the Environmental Protection Agency in preparing guidance for Federal agencies in the formulation of radiation standards and in issuing generally applicable environmental radiation standards. Although Reorganization Plan No. 3 of 1970 provides considerable flexibility in the form of the standards (limits on radiation exposures or levels, or on concentrations or quantities of radioactive materials in the general environment), it is silent on the methodology to be used in arriving at these limits.

In our September 15, 1975 comments to EPA on the proposed 40 CFR Part 190, we stated that: "The NRC staff believes that EPA's generally applicable environmental radiation standards should provide an upper limit for radiation exposures, predicated upon restricting the potential health impact from all sources of radiation exposure. The Nuclear Regulatory Commission would require its licensees to operate within such limits and further restrict effluent releases and radiation exposures in a cost-effective manner to be as low as reasonably achievable." Although we have accepted 40 CFR Part 190 which is based upon the cost-effectiveness of control technology, we still believe that such technology-oriented standards should be developed primarily by agencies with specialized expertise to assess the full safety, environmental, and economic consequences of such technology and that EPA should concentrate on defining allowable levels of radiation exposure based upon health protection considerations.

A second point that we raised in this letter, in subsequent testimony on 40 CFR Part 190, and in our June 28, 1977 testimony was the need for a uniform methodology for setting limits for all hazardous pollutants that might be released to the environment. This need exists not only for optimizing expenditures for controlling various sources of radiation exposure but also in the broader context of assessing the tradeoffs between alternate energy sources and in ensuring balanced expenditures for health protection and the optional use of finite available resources for environmental protection. The various statutes for environmental protection (such as the Clean Air Act, Federal Water Pollution Control Act, and Toxic Substances Control Act) should be investigated in order to determine whether a common and consistent approach toward environmental protection can be developed and employed. Suggestions for the development of a uniform approach are contained in our answer to Part (b) of this question.

(b) An amplification of two other recommendations would be helpful (i.e., (1) that requirements be written for the analysis of the value of proposed regulations, and (2) that guidelines be prepared for making judgments on the acceptability of risks).

Answer. (1) The two specific suggestions presented in our testimony follow from the more general recommendations elaborated upon in our reply to part (a) of this question.

A uniform methodology for assessing the value (and the economic, environmental, and sociological impacts) of proposed regulations is a necessary step toward increasing the effectiveness of governmental programs and optimizing the use of finite resources. Some efforts have been taken toward achieving this goal. One example is the guidelines issued as 40 CFR Part 1500 by the Council on Environmental Quality for preparation of the environmental statements required by Section 102(2)(c) of the National Environmental Policy Act of 1969. Another example is our own requirement for the preparation of a value/impact assessment on all proposed regulations and for the issuance of regulatory guidance on the format for submissions of license documents and for appropriate methods of complying with regulations. Although these value/impact assessments are not detailed numerical cost-benefit analyses, they do provide a means of evaluating the expected improvements in safety, health protection, and/or licensing efficiency against the possible increased cost of compliance and are made part of the public record.

A uniform approach for the preparation of such value/impact assessments, particularly for assessing the value of improvements in safety and health protection, for use by all Federal agencies would be beneficial to ensuring the optimal use of resources and a consistent regulatory approach throughout the Federal government. Some careful attention would need to be devoted to how best this approach could be developed and promulgated.

(2) The development of guidelines for a uniform method of setting of limits on allowable risks to health and safety is a prerequisite of a standardized approach to controlling all health hazards. As we envision these guidelines, they should first provide a methodology for evaluating the impact of various health effects on a consistent basis so that, for example, the increase in respiratory disease produced by fossil fueled power plants could be weighed against the risks of increased radiation exposure. One approach to evaluating the seriousness of increased mortality would be the amount of life-shortening that would result. Comparable measures would be required for evaluating the seriousness of increases in irreversible non-fatal illness and in reversible incapacitating injury in comparison to increased mortality.

A second important component of these guidelines would be the development of methodology for incorporating aesthetic and ethical considerations into the decision process of setting allowable risks to health and safety. A third component of these guidelines would be methodology for evaluating tradeoffs between purely economic considerations such as damage to building materials and those involving human ill health and damage to ecological systems. Lastly, these guidelines might consider the psychological aspects of the risks as perceived by the public and whether, and, if so, how such concerns should be factored into the decision process.

Question 3. In your testimony you mentioned the scientific and management roles of the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, the Office of Management and Budget, and the Environmental Protection Agency.

(a) To what extent does NRC follow the recommendations of these bodies in formulating agency regulations and protection guidelines?

Answer. The Atomic Energy Commission (which preceded the NRC) traditionally based much of its regulations for protection against radiation on the recommendations of the NCRP, the ICRP, and the FRC (whose functions are now in EPA). The NRC and AEC have not been required to accept the recommendations of the NCRP or ICRP and have done so only after due consideration of the recommendations by the AEC and NRC staff and through appropriate rulemaking procedures. The NRC is required to follow the regulations and guidance promulgated by EPA.

(b) In case of conflicting recommendations, how does NRC resolve these differences?

Answer. Rarely, if ever, have substantive differences been found among the recommendations of these organizations. Should differences exist, the NRC response would depend on the source and importance of the differences. Where conflicting opinions exist between NRC and EPA with respect to proposed regulations, attempts are made to resolve the differences during preliminary informal staff discussions and, subsequently, in formal rulemaking procedures which include public meetings.

Question 4. Your testimony suggests the desirability of assigning a lead agency role to EPA in radiation protection activities. However, the Committee has received testimony from EPA to the effect that many federal agencies have refused to cooperate in EPA's efforts to implement its present responsibilities. The Committee has great concern with this problem, especially since OTP-ERMAC's functions are now likely to be transferred out of the Executive Office.

(a) Would you recommend a lead agency role for EPA with respect to all sources of radiation?

Answer. Our testimony should be interpreted as encouraging EPA to take the lead in ensuring even-handed treatment of all industrial pollutants, including radioactive effluents. EPA's testimony that many Federal agencies refused to cooperate in efforts to implement EPA's present responsibilities only goes to highlight the need for an interagency framework to resolve issues which may be in dispute. Reasons for difficulties in this area may be jurisdictional questions as well as valid, differing technical viewpoints.

(b) Should the Federal Radiation Council be resurrected?

Answer. There is considerable merit in the suggestion to resurrect the FRC since it operated under procedures which ensured due consideration of the views of *all* Federal agencies and adequate procedures for resolving the differences in judgment which arise.

(c) How, specifically, could jurisdictional lines between the various agencies by more carefully delineated?

Answer. The present jurisdictional lines for radiation protection activities were established while the nuclear regulatory function was an integral part of the Atomic Energy Commission. The creation of the NRC as an independent regulatory agency, the possible transfer of the Office of Telecommunications Policy-Electromagnetic Radiation Management Advisory Council's (OTP-ERMAC) function out of the Executive Office, along with the ongoing Administration efforts to streamline the licensing of nuclear power plants makes this an appropriate time to review the existing jurisdictional lines between the various agencies and to identify areas of duplication and overlap that can be corrected. NRC would be pleased to participate with the other agencies involved in this effort.

Question 5. How many states have promulgated regulations pursuant to the suggested state regulations established by NRC and BRH? To what extent are the states controlling naturally-occurring or accelerator produced radioactive material? How uniform are these regulations from state to state?

Answer. All twenty-five NRC Agreement States have promulgated regulations for radiation protection using the suggested state regulations as a basis.

All Agreement States license the users of naturally occurring or accelerator-produced radioactive material. As noted in the NRC Task Force Report, NUREG-0301, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials" (NARM), an effective program for evaluating sources and devices containing these materials for source integrity and safe design is not being fully carried out. Such items and devices may be manufactued in States where there is no such regulatory program or are imported and then enter interstate commerce. Under the current regulatory structure, States cannot effectively control the distribution of NARM sources and devices which do not originate in their State. Many other sources have been distributed in the United States since the beginning of this century without effective regulatory controls. Agreement States have expressed special concern over the lack of uniformly applied standards governing the manufacture and distribution of these sources.

Naturally occurring radioactive materials associated with uranium mills are regulated by NRC for the duration of licensed activities except those under the jurisdiction of Agreement States where they are regulated by the States in a compatible manner. However, once the mill closes, and the license is terminated, the NRC has no authority over the remaining tailings.

As a matter of policy and practice, NRC reviews Agreement States' regulations prior to adoption, while in draft form, and when necessary, notifies the States of changes that are necessary to maintain compatibility with NRC and other Agreement State regulations.

Matters of compatibility normally include (a) basic radiation protection standards such as exposure limits, (b) definitions and table values, (c) regulations concerning distribution of generally licensed and exempt material, (d) regulations affecting licensees who operate in multiple jurisdictional areas, and (e) regulations equivalent to 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections." Minor variations in technical content occur, as do variations in format, organization, and codification which reflect the States' views and needs to carry out their statutory obligations and to conform with their administrative practices.

Question 6. It is the Committee's understanding that four federal agencies are currently researching the matter of regulating naturally occurring radioactive materials. Has there been an effort to coordinate this work? Has it succeeded?

Answer. An NRC Task Force completed a study on the matter of regulation of naturally occurring and accelerator-produced radioactive materials in June 1977.

The study was performed in response to requests received from the Agreement States and from the Conference of Radiation Control Program Directors that NRC acqire authority to regulate these materials. A copy of this report is being furnished to you in response to Question 1(a).

The Food and Drug Administration's Bureau of Radiological Health and the Environmental Protection Agency were invited to and agreed to participate by providing resource persons to the Task Force. Additional resource persons were provided by the Agreement States and by the non-Agreement States to represent their views. These individuals participated fully in the preparation of the Task Force report. The report recommended that the NRC seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials. NRC does not presently have such authority.

The report was published as an NRC document, NUREG-0301, and a notice of its availability and a request for public comments was published in the Federal Register in July 1977. In addition, the Chairman of the Task Force wrote to representatives of each of the Federal agencies identified or mentioned in the report to notify them of the report and to solicit their views and comments. Similar letters were also dispatched to all State Health Offices and to all State Radiation Control Program Directors.

We believe that, in this fashion, we will succeed in providing opportunities to other Federal and State agencies to participate in this study. All of the comments received supported the need for adequate regulation of naturally occurring and accelerator-produced radioactive materials. EPA stated that there is available within EPA the necessary authorities to provide radiation protection from naturally occurring radionuclides. We are analyzing all comments received.

Question 7. Since 1972, 600,000 gallons of high level radioactive wastes have been stored at the now-dufunct West Valley nuclear reprocessing plant in upstate New York. According to the General Accounting Office, the tanks are unsafe. The life of a tank is unpredictable; seismic criteria for the tanks are not being met, increasing the risk of rupture due to earthquakes; the vault in which the tanks are being stored may float, as it has before, again increasing the possibiilty of serious releases. Furthermore, the State of New York and the Federal Government must decide who has responsibility for the site; the waste itself must be analyzed; the techniques for tank removal must be investigated; and the future use of the site must be determined. How much money has NRC allocated for each of these serious problems? What level of manpower does NRC have working on these issues? At your present levels of funding and manpower, how soon do you expect that the situation at West Valley will be improved?

Answer. We are not aware of any statement by the General Accounting Office that the high-level waste tanks at West Valley are unsafe. The Comptroller General, in his report to the Conservation, Energy, and Natural Resources Subcommittee of the House Committee on Government Operations, dated March 8, 1977, discussed several West Valley topics that the Nuclear Regulatory Commission staff has been evaluating. The Commission's comments on the recommendations of that report were forwarded to the Chairman of the House Committee on Government Operations on June 9, 1977 (copy enclosed).

Being able to predict the life of a high-level waste tank precisely is not possible in the sense that one can categorically state the moment it will fail. General corrosion rates indicate a life well over one hundred years. Predictions of leakage caused by stress corrosion cracking are more difficult, but experience with other waste tanks in similar service indicate that leaks are not likely in the near future.

The high-level waste storage system, including the steel tanks and the massive reinforced concrete vaults containing the tanks, were originally designed and constructed to meet the then current regulatory criteria, the Uniform Building Code for Zone III, for seismically active areas. The current criteria provide that such facilities be designed to withstand the maximum vibratory ground motion that can reasonably be postulated to affect the site. Recent geologic investigations at the site have resulted in the establishment of a free field acceleration of 20 percent of gravity as the design earthquake loading. The Uniform Building Code approach did not utilize specific acceleration values as a design input; therefore, a direct comparison between the two approaches is not possible without substantial analyses. The purpose of our ongoing structural analysis of the high-level waste system is to determine whether or not the existing system design can satisfy the requiements imposed by the more recently derived criteria.

The risk, although not yet quantified, does not change with the establishment of new criteria. The seismic information gathered from investigations subsequent to initial licensing of the plant should be useful to the staff for better estimating the risk to the public from possible earthquakes near the site.

The word "float" has been used as a synonym for the uplift observed during construction. This condition was subsequently corrected before the tanks were commissioned. Because of the overburden pressures on the reinforced concrete vault, the waste storage system cannot float. With respect to these issues and others, the NRC staff has recently issued a report discussing the interim status of these ongoing evaluations. The report encompasses all of the activities at the site, including high-level waste storage. We have included a copy of this interim staff report for your use.

As co-licensees, Nuclear Fuel Services, Inc., and the New York State Energy Research and Development Authority have current responsibility for the site. It is our understanding that proposed legislation (S. 1811 and H.R. 6796) calling for a study by the Department of Energy (ERDA) concerning the various options for the site is awaiting consideration by the House.

In addition, we have requested ERDA support, either directly or through its prime contractor, on a number of key issues at the site. This support is discussed in the staff's interim evaluation report mentioned above.

Regarding the high-level waste in the tanks, the composition of the wastes is known from chemical analyses of the constituents in the reprocessing plant prior to transfer to the waste tanks. In addition, the supernatent is sampled and analyzed monthly. It is correct that the exact consistency and form of the solids content (sludge) at the bottom of the waste tank have not been determined. This information will be obtained as work progresses.

ERDA contractors, such as DuPont at the Savannah River plant, have been developing techniques for the removal of waste from tanks, including the precipitate sludges. It is not intended at this time that the tanks themselves be removed.

The NRC staff manpower assigned to the West Valley licensing activities consists of a full-time project manager with staff support in areas such as structural analysis. Considerable support has been provided by the Oak Ridge National Laboratory, Savannah River Laboratory, Battelle Pacific Northwest Laboratory, Los Alamos Scientific Laboratory, and Lawrence Livermore Laboratory in this area, either directly through contract with the NRC or in response to our request to ERDA for support. We estimate that approximately $195.000 will have been spent in support of NRC activities related to West Valley during Fiscal Year 1977. While no specific allocation is made to the resolution of each problem associated with the NFS facility, we anticipate a comparable level of support during fiscal year 1978.

Based on our evaluation, the risk to the public from the present dormant activity at the site is low. However, some contamination remains in the process cells and must be removed if the plant is no longer to operate. The future use of the site has not been determined, although Nuclear Fuel Services has indicated withdrawal from the reprocessing business. In response to our inquiry, they have indicated no intention to decommission, referring to the possible use of the site by the Federal Government. We intend to continue our evaluation of the site activities and cooperate with ERDA to develop a safe approach to the final disposition of the high-level waste.

Due to the complexity and number of issues involved, and the number of ongoing studies of which we are unable to predict the outcome at this time, we cannot project what the final action will be with respect to NFS, or when it will take place.

Question 8. The West Valley waste situation is not the only potentially hazardous one; 70 million gallons of similar high-level wastes are being stored at ERDA installations such as Hanford, Savannah River, and Idaho Falls. According to Science (Feb. 18, 1977), "Leakage of waste from some of the tanks at both Hanford and Savannah River has been a persistent problem . . . nearly 500,000 gallons of waste have leaked from the tank . . ." Does NRC have scientific evidence that shows that this leakage does not pose a significant threat to the public health? How much money and manpower has been spent or allocated to evaluating the dangers of tank leakage to man? To other forms of life? How much money and manpower has been spent or allocated to control the leakage of waste?

Answer. Based upon the evidence developed by ERDA, which is responsible for these facilities, the NRC does not see any threat to the public health from the leakages that have occurred. Since it was ERDA, the responsible agency, which has performed these detailed studies, the NRC is not able to provide information as to the manpower and expenditure in this area, including actual operational control.

Question 9. Various plans have been proposed for the removal of nuclear wastes from the biosphere, primarily the use of deep geologic repositories and the Retrievable Surface Storage Facitities. Is there scientific evidence that either of these methods provides a safe and effective way of disposing of nuclear wastes? Are there alternative methods of waste disposal being considered? How much money is NRC spending on nuclear waste disposal?

Answer. There is considerable scientific opinion that wastes may be safely disposed of in deep geologic repositories. ERDA has an active program to develop deep geologic repositories for the disposal of high-level nuclear wastes and other nuclear waste containing long-lived transuranic elements. The NRC, which is responsible for licensing and regulating the waste disposal facility developed by ERDA. is developing siting, design and operating standards for these repositories. A number of alternative methods of waste disposal are being considered by ERDA and the NRC will provide appropriate regulatory guidance for other waste disposal methods as it is required. Retrievable Surface Facilities may be used to store nuclear waste prior to disposal, but there are no present plans to use this type of facility for the disposal of nuclear wastes. The NRC is also developing siting, design and operating criteria for Retrievable Surface Storage Facilities to be used for interim storage of spent fuel and/or solidified high-level nuclear wastes. NRC's waste management budget and manpower are summarized below:

[Fiscal years]

	1975	1976	1977	1978
Thousands of dollars		343	4, 346	(5, 781)
Man-years		8	34	(40)

Question 10. "In your opinion, is there a need for national guidance and promulgation of federal standards for the siting, regulation, and care of the low-level radioactive waste disposal facilities?"

Answer. The NRC agrees there is a need for national guidance and promulgation of Federal standards for the siting, regulation, and care of low-level waste disposal facilities. As part of its program to re-examine the technical and regulatory bases for low-level waste management, the NRC established a Task Force to review the programs of the NRC and States for regulating the disposal of commercial low-level wastes. This Task Force recommended that the NRC, in cooperation with appropriate Federal and State agencies, should accelerate development of the regulatory program for disposal of low-level wastes.

The report of the Task Force was published in March 1977 (NUREG–0217, copy enclosed), and the conclusions, recommendations and body of the report were published in the *Federal Register* to solicit public comments. Thirty-three comments were received from Governors, State agencies, industry representatives and other interested parties. All commenters and the NRC agree that comprehensive standards and criteria for low-level waste disposal are needed. The NRC waste management program being implemented includes the development of a comprehensive regulatory program for low-level waste disposal, necessary supporting research, and consideration of alternative disposal methods. The program has as its goal the development of regulations by 1980 for shallow land burial of low-level radioactive wastes, and by 1981 for alternative waste disposal methods.

Question 11. Has the NRC tried to ensure the neutrality and objectivity of the group which is to review the adequacy of the Rasmussen Report? What is the projected cost of this review? What was the cost of the Rasmussen Study?

Answer. The members of the Risk Assessment Review Group were selected on the basis of their ability to contribute to an informed discussion and analysis of the peer comments on the WASH–1400 report. In making these selections, NRC gave consideration to the need for a balanced view on the Group. The membership includes those who have been critical of the report, those who have praised it, and those who have not taken a specific position on it.

In addition, the selection of Dr. Harold H. Lewis as Chairman gave further assurance of the Group's independence, since Dr. Lewis is well known for his objectivity and independent judgment.

The projected cost of this review is approximately $30,000, which covers payment of travel, per diem and other related expenses. The cost of the Rasmussen Study, including both the draft and final reports was approximately $4 million. This covered a 3 year period and included computer costs, and payment for approximately 100 people who worked on the study.

Question 12. (a) What is the current status of plans to evacuate and protect the public in the event of an accident at a nuclear power facility?

Answer. All nuclear power plants, prior to being issued an operating license, are required to have an emergency plan for coping with accident consequences both onsite as well as in the environs of the nuclear facility. Such plans must meet the requirements of the Commission's regulations set forth in Appendix E to 10 CFR Part 50 and provide reasonable assurance that appropriate protective measures can and will be implemented in a timely fashion for protecting the public health and safety. All existing licensees' emergency plans meet these requirements and are interfaced with the response capabilities of Federal, State, and/or local authorities, including particularly those having jurisdiction for implementing protective actions, including evacuation, in the potentially affected areas. All licensees' plans contain agreements with the appropriate response organizations together with provisions for notification in the event of and accident having potential offsite consequences. Additional assurance for maintaining the emergency preparedness posture of the offsite response agencies is provided through the NRC inspection program which not only contacts these agencies prior to the issuance of a license but also periodically thereafter. The States with operating reactors all have emergency plans and NRC and other Federal agencies are currently assisting in upgrading these plans to meet the "standards" set forth in our guidance publication NUREG–75/111 and Supplement No. 1 to this publication (copy enclosed).

(b) What percentage of communities located near nuclear power facilities have prepared such evaluation plans?

Answer. The specific protective measure of evacuation of the plant environs is provided in all licensees' emergency plans. In the licensing process, great emphasis is placed upon those aspects of such plans which address the question of when to evacuate, how large an area to evacuate, and who is responsible for initiating and carrying it out, rather than on questions of the mechanics of the process. All communities have an ability to carry out evacuations but plans for evacuation are neither elaborate nor complex. Experience with real evacuations related to natural disaster situations and chemical release accidents has shown no benefit can be expected to be derived from elaborately prepared evacuation plans. During its review of the suitability of each particular site to accommodate a proposed nuclear power plant, the Commission staff does evaluate the feasibility and practicability of carrying out evacuations in the nearby environs.

(c) Has the feasibility of such evacuations been tested?

Answer. Since the civil authorities in this country have effectively demonstrated their capabilities to evacuate the public in times of disaster many times, NRC does not believe that testing evacuation plans to the point of actually moving members of the general public is desirable. The Commission has analyzed the competing risks involved in an evacuation drill compared to that of the potential reactor accident, and has concluded that the involvement of the public in an evacuation exercise is not warranted from a risk-benefit viewpoint. In addition, comments from State and local government agencies on a petition for rulemaking to require actual evacuation drills indicate firm opposition since there would be large impacts on people and problems in protection of private property. However, licensees' plans contain provisions for periodic test exercises which include the participation of offsite emergency personnel including those of State and local government agencies. As a minimum, such exercises test the communication links and notification procedures with those agencies to demonstrate that capability for early warning of the public is maintained.

(d) Have the local authorities been trained in the handling of such an evacuation?

Answer. It is recognized that the various offsite support services which could be activated in the unlikely event of a serious radiological accident may require specialized training particularly in those aspects which are radiological in nature. Consequently the NRC together with other Federal agencies is involved in the development and conduct of emergency preparedness programs for training State and local government personnel. These training programs cover both radiological emergency response planning and operations. To date, hundreds of State and local personnel have participated in these programs. In addition, the NRC heads the Federal Interagency Field Assistance Cadre which provides field assistance to State and local governments for the development and improvement of radiological emergency response planning. The Cadre at the request of the State also observes field emergency response exercises conducted by State and local governments in support of nuclear facilities and provides evaluations of these drills to the participating agencies.

Question 13. Please provide documentation for your remark that after the publication in 1971 of a regulatory guide on occupational exposure at nuclear power plants there was a marked improvement in operational design.

Answer. My discussion was that after publication in 1971 of the "as low as practicable" (ALAP) requirement on occupational radiation exposure, as part of 10 CFR Part 20, implementation guidance was provided by the issuance of a regulatory guide. This was Regulatory Guide 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Plant Stations Will be as Low as is Reasonably Achievable" (ALARA), which was first issued in July 1973. This guide did represent the first formal implementation of the ALAP approach.

Regulatory Guide 8.8 sets forth particular design, construction, operational, and procedural aspects of the plant and its proposed operation, which are intended to assure that full consideration is given to keeping occupational radiation exposures as low as is reasonably achievable. As a result of this guidance, applicants for power reactor construction permits and operating licenses have introduced a number of innovations in design and operational features to reduce occupation exposures. These are reviewed by our staff as part of the licensing review process. The provisions are described in Chapter 12, Radiation Protection, of the Safety Analysis Report submitted by applicants, and these descriptions constitute the main source of documentation that marked improvements have occurred.

As a further result of Regulatory Guide 8.8, utilities, architect-engineer firms, nuclear steam system suppliers, and other system vendors have hired health physicists and established corporate health physicist staffs to help during the design and construction phases on features and procedures that will minimize radiation exposures resulting from plant operation. Reactor vendors have instituted measures such as specifications of materials with low cobalt impurity for systems in contact with primary coolant to minimize activated corrosion products (CRUD), the main source of inplant doses. Vendors have also studied and removed high cobalt wear materials where possible. Utilities, vendors, consulting firms, and contractors have developed special tools and procedures to allow many necessary tasks at reactors to be performed with less occupational radiation exposure. An example of the special tools and procedures developed are those for remote steam generator tube eddy current testing. Also, many firms have developed equipment training mock-ups and improved methods for radiation protection training. The architect-engineer firms are now placing much more emphasis on in-plant radiation protection in plant design. Many of the specific design improvements are the result of efforts by these firms to reduce occupational radiation exposure by more than just shielding.

We feel that a major area of improvement is the practice of incorporating the principles of radiation protection in the design from the beginning. Utilities and architect-engineers have developed ALARA design guidelines for use by individual designers. Radiation protection design groups study experience from operating reactors and incorporate that experience into new design and procedures to reduce exposure. And as the design proceeds, reviews are conducted by personnel of various disciplines including radiation protection to determine if there are any changes which might help reduce exposure.

The design of older plants caused significant radiation protection problems in maintenance activities. Many components containing radioactivity were crammed into each shielded room. When maintenance became necessary, one was faced with high radiation levels and difficulties with physical access. Today, design features to reduce exposure are directed at (1) reducing the need for maintenance, (2) reducing the time needed to perform necessary maintenance. and (3) reducing the dose rate which the workers are exposed to in performing the maintenance.

Shield walls are designed and built with knock-out concrete block sections to facilitate removal of large components when necessary. Labyrinth entrances to cubicles are sized to allow equipment access and equipment laydown maintenance. Instrument panels which must be accessible are shielded from the radiation sources. Valve handwheels are shielded from the high-dose-rate valves and associated piping. Piping is run in shielded pipe chases. Liquid filter cubicles have shielded hatches through which filter element replacement can be performed remotely with special tools.

These and many other innovative responses to the concepts in Regulatory Guide 8.8 have been presented in the radiation protection description (Chapter 12) of various Safety Analysis Reports, including those for standardized designs. In addition, examples have been discussed by vendors and utilities in presentations before the Advisory Committee on Reactor Safeguards. Transcripts of these meetings are in the Public Document Room at NRC.

Thus, we have seen an increasing awareness in the industry of the need to reduce unnecessary occupational radiation dose. We expect that this process will lead to continuing further reduction of doses at power reactors in a cost-effective manner. Results will not become evident until a number of these plants actually go into operation.

Question 14. Your description of NRC's interface with OSHA is unclear. There are "NRC agreement states" and "OSHA agreement states". Citations are issued according to the source of radiation. Is this enforcement mechanism practical? Do you know if violations are being reported under such a scheme?

Answer. "NRC Agreement States" are those States which have entered into agreements with NRC pursuant to Section 274(b) of the Atomic Energy Act, as amended. Under such an agreement, the NRC discontinues, and the State asserts its authority over any one or more of the following: (a) byproduct materials, (b) source materials, and (c) special nuclear materials in quantities not sufficient to form a critical mass. These States, and the dates they became Agreement States are as follows:

State	*Became an Agreement State on*
Kentucky	March 26, 1962.
Mississippi	July 1, 1962.
California	September 1, 1962.
New York	October 15, 1962.
Texas	March 1, 1963.
Arkansas	July 1, 1963.
Florida	July 1, 1964.
North Carolina	August 1, 1964.
Kansas	January 1, 1965.
Oregon	July 1, 1965.
Tennessee	September 1, 1965.
New Hampshire	May 16, 1966.
Alabama	October 1, 1966.
Nebraska	October 1, 1966.
Washington	December 31, 1966.
Louisiana	May 1, 1967.
Arizona	May 15, 1967.
Colorado	February 1, 1968.
Idaho	October 1, 1968.
North Dakota	September 1, 1969.
South Carolina	September 15, 1969.
Georgia	December 15, 1969.
Maryland	January 1, 1971.
Nevada	July 1, 1972.
New Mexico	May 1, 1974.

"OSHA Agreement States" are those States which have OSHA-approved occupational health and safety regulatory program. Section 4(b)(1) of the Occupational Safety and Health Act of 1970 excludes from the coverage of that Act "working conditions of employees with respect to which other Federal agencies and State agencies acting under Section 274 of the Atomic Energy Act of

1954, as amended, (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

In NRC Agreement States, the same regulatory requirements and practices that are applied to users of byproduct, source and special nuclear materials (so-called agreement materials) are applied to users of other radioactive materials, including naturally occurring and accelerator-produced radioactive materials. In some NRC Agreement States, OSHA standards and enforcement practices are applied to users of other radioactive materials with respect to working conditions (this includes a separate set of radiation protection standards). We have worked with the Department of Labor and the NRC Agreement States to avoid dual citations and enforcement actions in those states which have agreements with both agencies. NRC is not routinely informed of violations of State-OSHA standards. We are, however, aware that citations are being made.

We do not consider the application of State-OSHA requirements to non-agreement material licensees in Agreement State to be practical or to have special merit. State OSHA radiation protection standards do not provide for pre-evaluation of uses under a licensing program, cover releases of radioactive materials to the environment, or establish permissible levels of radiation outside the workplace, e.g., a waiting room adjacent to a nuclear medicine laboratory. For these regulatory areas, the affected State must make reference to its "other" radiation protection standards, specifically, the regulations which were prepared by following the Suggested State Regulations and which have been reviewed by NRC for compatibility (see response to Question No. 5).

Question 15. You discussed a plan, adopted by NRC in February, 1977, to strengthen the program to eliminate unnecessary occupational exposures which might occur throughout the full range of activities NRC regulates. The major elements of this broad plan (i.e., written exposure control programs, minimum training requirements for workers, requiring employment of radiation protection personnel in both design and operational phases of the nuclear facilities) appear to be *minimal* features which should have been imposed upon licensees when the industry was in its infancy. Why has NRC or its predecessor AEC declined until now to incorporate such measures into its safety program?

Answer. The plan adopted by NRC in February 1977, to strengthen the radiation protection program to eliminate unnecessary occupational radiation exposures and to maintain such exposures as low as is reasonably achievable (ALARA), includes as major elements written exposure control programs, minimum training requirements for workers, and consideration of radiation protection factors in both design and operational phases. These features are not new, but rather have been an important part of considerations in the license application review process from the beginning. The program adopted places increased emphasis on these important features by providing more specific and detailed guidance as to the information that the NRC staff considers necessary in the applications and distilling the experience obtained with previous and existing designs. In this way we hope to achieve a greater awareness of the occupational radiation exposures, reduced exposures, and a greater degree of uniformity in the effort expended in maintaining occupational exposures ALARA.

Question 16. (a) How carefully is data gathered in the nuclear industry on the exposure of workers to ionizing radiation?

Answer. The Nuclear Regulatory Commission and its predecessor, the Atomic Energy Commission, have required the submission of annual reports on personnel monitoring from four categories of licensees since December 1968. These four categories are power reactors, industrial radiographers, fuel processors and reprocessors, and certain large commercial suppliers of byproduct materials. The licensees in these four categories were considered the principal potential source of significant occupational radiation doses. The data submitted by licensees pursuant to this requirement (10 CFR § 20.407) are summarized in annual reports. A copy of NUREG-0119, "Eighth Annual Occupational Radiation Exposure Report 1975," is enclosed. The ninth annual report, relating to monitoring experience in 1976, is to be published in the near future.

In May 1975, NRC published a notice of proposed amendment to its regulations that would, if adopted, extend to all licensees the requirement for the submission of an annual statistical summary report on personnel monitoring data. Comments on the proposed amendment raised questions regarding the value of the data to be obtained and the burden of reporting on licensees. In order to provide the NRC with a better basis to evaluate (1) the benefit to be obtained from extending the reporting requirement to all licensees, and (2) the burden that the proposed extension of the reporting requirement would impose on licensees, and to test the assumption that the four categories of licensees currently reporting represent the greatest potential for significant doses, NRC requested all "other" licensees to submit as a voluntary, one-time action, a statistical summary report of the whole body personnel monitoring results for their activities during 1975. This request was made by letter dated August 25, 1976. Responses were received from about 1,180 licensees (about 14% of the total number of "other" licensees), and a report on these data is in preparation.

More detailed information on radiation exposure experienced at nuclear power plants, including data on exposure according to job function, has been obtained from reports required by technical specifications imposed on those licensees. This information has been published in a series of reports, the latest being NUREG-0109, "Occupational Radiation Exposure at Light-Water Cooled Power Reactors 1969–1975."

(*b*) Have studies been established to monitor long-term health effects in such workers?

Answer. Studies have not been established to monitor the long-term health effects on the individuals employed by NRC licensees in jobs involving radiation exposure. Such effects have been investigated over a period of many years for individuals involved in AEC-contractor operations by Dr. Mancuso and others, and are being followed and studied closely by the NRC staff (Also see response to Question 21.).

(*c*) What is the average annual exposure of nuclear industry workers at the present time?

Answer. The "voluntary" data submitted by "other" licensees as described in (a) above indicate an average of 0.1 rem per individual monitored by such licensees. The comparable average monitoring result per individual among the four categories of licensees currently required to report was 0.36 rem in 1975.

Question 17. (*a*) According to a *Washington Post* article on the Apollo plant: "There were seven cases of individual exposures exceeding regulations. Yet, 'Reports were not furnished to six individuals notifying them that they had been exposed to radioactive material in excess of that permitted by regulations.' " Why were these workers not informed?

Answer. The workers knew of their overexposures when they occurred and all the exposures in question were reported to the NRC in 1973. However, due to an administrative oversight by NUMEC management, the required notification letters were not sent to six of the employees. After the discrepancy was noted during an NRC inspection in March 1974, the individuals were notified in writing on an approved notification form.

(*b*) Furthermore, the report states that the Apollo factory's sewer system "repeatedly leaked excessive amounts of uranium into Kiskiminetas River near the plant." How much radioactivity was involved? What actions have been taken to rectify this situation?

Answer. In 1970 and 1971 routine releases of liquid effluents from the plant to the Kiskiminetas River were found to exceed specified limits due to short half life thorium nuclides. The release levels did not reach twice the amount permitted in NRC regulations. Since the regulatory limitations are established on a conservative basis, the NRC does not consider the amounts released during the period in question as posing an undue threat to the public health and safety.

Since 1971 the liquid effluents released from the facility have been stored for a time interval sufficient to allow the short half life thorium nuclides to decay to acceptable release levels prior to release to the river.

(*c*) Supposedly, some of the 400 workers at the Apollo factory were exposed to high levels of radioactivity by leaks of uranium compounds. How serious were these exposures? What is the present state of health of those workers? How did this accident occur?

Answer. All these exposures exceeded weekly limits. In one case, the exposure exceeded weekly limits averaged over one quarter. In all cases, these exposures did not exceed the "permissible" annual cumulative exposure to airborne radioactive materials permitted by NRC regulations. (The weekly reporting method was changed to a quarterly reporting method in December 1976.) Only one of these exposures would have been a reportable incident under the revised regulations. Significant health effects have not been observed as a result of exposures of these magnitudes.

To the best of NRC staff's knowledge, the health of these individuals has not been and would not be expected to be altered by these exposures.

The exposures in question did not occur from a single accident. They resulted from separate minor malfunctions during routine operation of the facility.

For additional detail on these exposures see response to Question 1(e).

Question 18. A recent release by the NRC noted plans to increase the stringency of security measures involved in the protection of nuclear materials. In this case, NRC appears to be following some of GAO's recommendations in a report titled, "Commercial Nuclear Facilities Need Better Security." Has NRC attempted to follow any of GAO's other recommendations, such as clearly defining the use of firearms by security guards or changing its procedures to monitor accounting of special nuclear materials by individual material balance area?

Answer. The use of deadly force by private guards at commercial nuclear facilities has been carefully considered. The NRC believes that if a guard on duty at such a facility killed or wounded a person, the killing or wounding would be deemed justifiable or not based on the law of the State in which it occurred.

Our experience with licensees and our research has shown that considerable variation in state law exists on the question of justifiable homicide, which is the legal context in which one must consider the use of deadly force. However, in the narrow context of private guards doing their job on private property, we have distilled three major aspects of justifiable homicide that we think are universally acceptable in this country and that can, accordingly, be embodied in a rule of general application. The first is that the guard has no duty to retreat from a show of force, or from a situation that could lead to use of force. This principle we have embodied in our proposed response rule (42 FR 8382) in a requirement that the guard interpose himself between the adversary and material area or vital areas subject to attack. He is also required to intercept anyone exiting with material. A second principle is that guards may generally meet force with force. This principle we also state in the proposed response rule. Finally, we find general acceptance of the use of deadly force when there is a reasonable belief it is necessary in self-defense or defense of others against adversaries. These three permissive principles, taken together, are included in current license conditions and in a proposed amendment to 10 CFR Part 73 which was published for public comment on February 10, 1977 (42 FR 8382).

With regard to NRC's procedures to monitor accounting of special nuclear materials, a task force has been established to determine: the role of material control and accounting in the NRC safeguards program, the contributions to safeguards provided by current methods, possible weaknesses of current methods, performance criteria for material control and accounting, and needed improvements in the material control and accounting program. The findings of this task force may provide a basis for possible changes in NRC material control and accounting requirements.

Question 19. Although NRC has sought to increase the security of nuclear materials, there is also danger from the present non-compliance levels of nuclear facilities. The case history of the Apollo plant shows that nearly every inspection has revealed severe problems in internal material accounting procedure. However, it seems that only one fine of about $12,000 was imposed over this period, despite the large number of violations. Were any other disciplinary actions taken? If not, why? What is NRC's present attitude towards the loss of strategic nuclear materials? Will harsher penalties lessen the degree of noncompliance? Does the present situation constitute a health hazard to the public or employees?

Answer. A review of the Inspection and Enforcement records for the past four years shows that 69 inspections were conducted at the Apollo plant and 157 items of noncompliance were identified. Of these items of noncompliance, 2 were of the most significant violation category, 100 were infractions of the next lower category of safety significance and 55 were deficiencies or the lowest category of noncompliance. The 55 deficiencies had very minor safety significance; consequently, most of these matters were corrected in response to "Notices of Violation" from the Office of Inspection and Enforcement.

As a result of these inspection findings, the AEC imposed a civil penalty in the amount of $12,170 on August 12, 1974, and the NRC imposed a civil penalty of $19,000 on July 23, 1976. The first of these penalties involved both safeguards and safety matters while the latter penalty involved items of noncompliance related only to safeguards. In addition to the two civil penalties, the AEC's predecessor to the Office of Nuclear Material Safety and Safeguards issued an order on March 11, 1974, requiring the licensee to modify its license and develop and implement an adequate security program. It was subsequently determined that this was accomplished in the time required. Another order was issued by the Office of Inspection and Enforcement to the licensee on February 28, 1977, requiring the licensee to reconcile its inventory of highly enriched uranium and the licensee complied with that order. In each instance where noncompliance was identified, the NRC has taken enforcement action commensurate with the significance of the problem in order to assure prompt corrective action.

NRC believes that loss of strategic nuclear material is a serious matter. Our regulations require that material which cannot be accounted for should not exceed the small errors encountered in the measurement process. When our limits are exceeded, we see that appropriate action is taken to determine the cause. Due to the complex nature of the chemical process in nuclear fuel fabrication facilities and the inherent uncertainties in the measurement of the nuclear material, inventory differences are expected to occur. The NRC and the licensee evaluate these inventory differences for significance. All inventory differences, whether an apparent loss or gain of nuclear material, are evaluated.

A large inventory difference which exceeds its associated measurement uncertainty may be an indication of processing problems, biased measurements, bookkeeping errors or a loss or theft of material. Accordingly, NRC requires licensees to take increasingly strongly investigative actions depending on how much the inventory difference exceeds LEMUF (the limit of error for materials unaccounted for). The NRC relies on evidence provided not only by the material accounting system but also by the internal control system, the physical security system, NRC inspections and evaluations, and NRC and licensee investigations. These safeguards systems are designed to alert company management and NRC to processing problems and material losses and to help determine whether an inventory difference is the result of an accounting error or a measurement problem or the result of a loss or theft of nuclear material.

We have considered invoking harsher civil penalties as an enforcement tool to assure a greater degree of compliance with Commission regulations. To that end we have engaged a consultant to make a study of existing sanctions and other available incentives that may be adopted by the NRC. This study should be completed within a few months and should recommend whether civil penalties are an effective tool and whether such penalties should be increased. If it is determined that civil penalties should be increased, we will recommend a change in legislation to permit larger civil penalties.

The present state of operations at Apollo does not constitute a health hazard to the public or employees. The licensee monitors the concentrations of radioactivity in the air at work locations, the external radiation levels inside the plant and its personnel to assure that employees are not exposed to doses in excess of regulatory limits.

In regard to discharges to the atmosphere, the B&W Company monitors these discharges through the use of continuous air samplers and the taking of specific and periodic environmental samples, including soil and vegetation. Any one of the above sampling methods should detect discharges above maximum permissible concentrations. The NRC inspects these sampling programs to ensure that they are conducted adequately and also reviews program results to ascertain that NRC limits are met. In addition, the NRC has verified, by independent measurements, the capability of B&W to measure these effluents.

In regard to discharges to the river, the normal discharges from the B&W site are a few percent of the maximum permissible concentrations. In the year 1970 and before, there were several problems involving the discharge of short-lived thorium isotopes. These problems were resolved by engineering changes that include modifications to the waste treatment system and by the temporary storage of these short-lived radioisotopes. The NRC has also verified, by independent measurements, the capability of B&W to measure these effluents.

If the material unaccounted for had been discharged to the river, it is calculated that the amount released would not exceed 5 percent of the maximum permissible concentrations. It is appropriate to note that the radioactivity in the river from natural sources far exceeds the contribution from B&W uranium operations.

Question 20. (*a*) What emission levels are currently being released by operating light-water nuclear power reactors?

Answer. Releases of radioactive materials from operating light-water nuclear power reactors are being maintained at a small fraction of the technical specifications appended to operating licenses. The Nuclear Regulatory Commission publishes regular summaries of radioactive materials released from operating light-water nuclear power reactors. NUREG–0218, "Radioactive Materials Released from Nuclear Power Plants (1975)," is the last published summary, and is included as an attachment to this response. A summary of releases in 1976 is in draft form, and is being reviewed by the NRC staff. A preliminary analysis of these data indicate that releases generally have continued to be small, with a number of licensees reporting even lower release levels in 1976 than during 1975. The sources of data included in the above summaries are individual radioactive release reports, submitted to the USNRC in accordance with 10 CFR § 50.36a. Copies of individual light-water nuclear power reactor radioactive release reports, covering plant startup through the period June 30, 1977, are available in the Nuclear Regulatory Commission Public Document Room at 1717 H Street, NW., Washington, D.C. 20555.

(*b*) Is it feasible to reduce further these emission levels?

Answer. On May 5, 1975, the Nuclear Regulatory Commission announced its decision to meet the criterion "as low as is reasonably achievable" for radioactive material in light-water-cooled nuclear power reactor effluents by adopting, in a rulemaking proceeding, numerical guides for design objectives and limiting conditions for operation. This decision is set forth in Appendix I to 10 CFR Part 50.

Currently, the NRC staff is reviewing all operating light-water nuclear power reactors for conformance with the requirements of Appendix I to 10 CFR Part 50. Based on the review we have completed to date, we have determined that all of the facilities meet the requirements of Appendix I. It is possible for these facilities to further reduce the emission levels; however, it is not cost-effective and not required by the regulations—that is, the point is reached at which the cost of further reduction of emissions of radioactive material are not justified in terms of real benefits to the public. In reality, the effects associated with releases at the regulations' design objective level, are insignificant, and these facilities are expected to operate with emissions below the levels set forth in the regulations.

The staff is in the process of developing new technical specifications for each reactor to provide reasonable assurance that releases of radioactive materials in liquid and gaseous effluents are "as low as is reasonably achievable" in accordance with 10 CFR § 50.34a and 50.36a.

(*c*) To what extent is there independent verification of the emission level numbers provided to the NRC by individual power facilities?

Answer. The NRC, through the Office of Inspection and Enforcement routinely conducts (on an annual basis) a confirmatory measurements inspection program in which radioactive effluent samples from nuclear facilities are independently analyzed by the NRC or the NRC reference Laboratory and compared with the licensee's measurement capability. The objective of this program is to determine the licensee's capability to make accurate measurements. (The measurements are made on the same sample or portions of the same sample of actual effluents taken in the plant.) The samples analyzed in the program included liquid, gaseous and particulate effluents. Occasionally, we also require the licensee to measure the radioactivity in the stimulated samples prepared by the NRC's reference Laboratory. In particular, simulated samples are used prior to plant operation in order to evaluate the licensee's capability to accurately measure effluent samples.

(*d*) Should monitoring efforts by independent agencies be expanded?

Answer. The NRC as an independent agency, as discussed above, conducts an inspection program to verify the licensee's effluent measurements and in addition, it also reviews and evaluates the sampling equipment and procedures used to collect and analyze samples. Additional independent verification samples could be useful in better defining licensee's capability. However, at the present level, we believe the NRC obtains adequate assurance that the licensee's measurements are reasonably valid.

Similarly, the NRC inspects the environmental monitoring program conducted by licensees. To check the operation of licensee programs, the NRC has contracts or agreements with 16 States to collect and/or analyze environmenal samples from the environs of nuclear facilities. The samples are usually duplicates or portions of the samples analyzed by the licensee. The NRC-State monitoring program is supplementary to the State's own surveillance program.

NRC has entered into an interagency agreement with EPA in which EPA has agreed to be more responsible to NRC's needs relative to checking the analytical accuracy of licensees and their environmental contractors. Most NRC power reactor licensees and their contractors currently paticipate in the EPA program on a voluntary basis. However, NRC will soon require, through provisions in technical specifications for each reactor, participation in this program. Under the program, EPA provides to the licensees various standard test media with unspecified radioactivity levels. Licensees or their contractors analyze these samples and report the results to EPA. If discrepancies are found in their analysis, licensees must take corrective action and report to the NRC. NRC will inspect these samples for compliance.

Question 21. In 1972, the BEIR report gave its stamp of approval to the linear hypothesis; since then, new doubts have been raised. Articles by Dr. Irwin Bross, Drs. Mancuso and Stewart, and Dr. Ernest Sternblass seem to indicate that the problem of effects at low levels of exposure is more serious than the linear hypothesis would predict.

(*a*) Is there a need to reexamine the linear hypothesis?

Answer. The staff is in the process of arranging an open meeting at which Dr. Bross will present the results of his work. At this meeting it is anticipated that Dr. Bross' work will be reviewed by an independent epidemiologist and open discussions will be held. This will take place during FY 1978.

More specifically related to reexamination of the linear hypothesis is an EPA-funded study by the BEIR Committee. This study (Contract No. 68-01-4301, Alterations to General Provisions 1900-28 (July 1976)) will be completed in fiscal year 1979. The portions of the statement of work directly relating to the linear hypothesis are as follows:

"The Contractor shall review the current state of knowledge of somatic and genetic effects of ionizing radiation. Under this review phase the Contractor shall consider the following:

"*Phase 1*

(A) ----------

(B) Recent theories of curvilinear dose response functions for both high and low LET radiations for somatic and genetic effects.

(C) The effects of dose rate and protraction on the incidence of radiation effects from high and low LET radiations for somatic and genetic effects.

(D) ----------

(E) ----------"

The staff anticipates that the new BEIR report will contain recommendations as to whether or not the linear hypothesis remains as a conservative method of estimating health effects of radiation.

(*b*) Have funds been spent in fiscal year 1977 for this purpose?

Answer. NRC has not expended any funds in fiscal year 1977 for projects directly related to the reexamination of the linear hypothesis, other than the review of the Mancuso and Stewart work referred to in the answer to question 21(c).

(*c*) Are funds budgeted in fiscal year 1978?

Answer. The NRC has relied on the BEIR report for its evaluation of the health effects of low dose and dose rate radiation. However, the staff has examined the work of Mancuso and Stewart and will be funding independent research on the AEC/ERDA Health and Mortality Study of which the Mancuso-Stewart data are a part. This work will be carried out during fiscal year 1978 and future years.

Question 22. EPA has revised the uranium fuel cycle exposure standard to 25 mrems/yr.

(*a*) Does NRC comply with this standard?

Answer. Although most NRC-licensed uranium fuel cycle facilities already are in compliance with this standard, compliance is not required before December 1, 1979. This lead time is required for NRC to identify and make the necessary modifications to its regulations and licensing conditions to implement the standard while affording adequate opportunity for public comment.

(*b*) If the new evidence on the non-linear hypothesis is considered valid, would NRC revise this standard further?

Answer. If new evidence on the radiation dose-effect relationships suggests that the standard should be revised, we would request EPA to reexamine the standard rather than NRC modifying it unilaterally.

Senator STEVENSON. Our next witness will be Dr. James Liverman, Assistant Administrator for Environment and Safety, Energy Research and Development Administration.

STATEMENT OF DR. JAMES L. LIVERMAN, ASSISTANT ADMINISTRATOR FOR ENVIRONMENT AND SAFETY, ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION; ACCOMPANIED BY RICHARD KENNEDY, OPERATIONAL AND ENVIRONMENTAL SAFETY DIVISION; AND BILL BROBST

Dr. LIVERMAN. I have with me Mr. Richard Kennedy, from our Operational and Environmental Safety Division, and Mr. Bill Brobst, who is working with our transportation problems.

With your permission, I will submit the statement for the record and run through a few slides rapidly to show you something of the breadth of the program we have.

Senator STEVENSON. Without objection, the full statement will be placed in the record.

Dr. LIVERMAN. We have the largest program in the country in the radiation area. It would take me more time than I think we have to go into detail on it. However, I would like to give you a broad impression of it.

This first slide is an attempt to show the nuclear fuel cycle, which would give some impression of the kind of——

Senator STEVENSON. Wait a minute. That doesn't show anything.

Dr. LIVERMAN. We can proceed without the slides.

The first slide was an attempt to show the uranium fuel cycle. We begin with uranium mining, take it through a milling process, convert it to uranium hexafluoride which is enriched in a uranium enrichment plant, and fabricated into fuel for use in a reactor. The spent fuel is then shipped and disposed of.

In view of the recent decision on the part of the President to slow down reprocessing and the breeder activity, we are not at this moment concerned with the reprocessing issue, except as it relates to the weapons program.

Basically, once the material begins the fuel cycle at the uranium mine, we become concerned about a number of different things. We become concerned about the control technology, about the biomedical and environmental effects and the related processes, and we become concerned about the operational safety. You have been going into questions related to that.

In the biomedical and environmental area, you have to determine what the characteristics are of the radiation, whether it be from a fixed point source or from a radioactive isotope that might occur in the environment.

So you characterize and measure it. You take a look at how it moves through the environment: land, air, water. Finally, the ultimate question one must try to address is, in human health studies and experimental animal studies; namely, what are some of the effects?

Obviously, in order to understand these effects in any detail, one needs to look at, not only the whole animal and the whole human, but the cellular and molecular levels to see what is taking place in the cell itself.

Basically, then, the programs for which I am responsible—which constitute a major segment of those in the country—have to do with that whole spectrum of the fuel cycle—taking it from the beginning of the process at the mine mouth and carrying it all the way through to the ultimate disposal process, looking at the biomedical/environmental questions that arise along the way.

One of the major issues we have had to face is: how can we be reasonably certain that we have taken into account most of the issues that have to be taken into account?

To do that, we have developed what I will refer to as an environmental planning process. In this planning process we get together around the table, the biomedical and environmental people with the technology people, to hammer out what the issues and concerns are that are of importance and must be dealt with during the course of the development of that technology and, particularly, for its implementation.

One becomes concerned about the control technologies: how do you limit the amount of releases; concerns about the movement in the environment, and where it collects; concerns about health, particularly occupational health but also general health; and about the institutional questions.

Out of that environmental development planning process then, we identify the kinds of questions that must be answered if the technology is going to be used safely and cleanly.

You have, yourselves, this morning enumerated a number of different agencies with activities going on in the radiation area.

One of the things we have done—and I would like to submit a summary copy for the record—is to try to inventory all of the research in the environmental, health, and safety areas, going on not only in the radiation area but in all areas of environmental, health, and safety as related to all of the techologies ERDA is developing to see what is being done by various agencies and by ERDA on such issues as mining and milling, fuel reprocessing, waste management, transportation, and related activities.

If one wants to take, say, a specific issue like economical waste management within radiation protection standards, and a number of requirements, like return waste solidification processes, investigating gaseous waste storage, evaluating federally controlled sites and related questions, and to take these down to specific projects, to discuss—say, for instance, the health and genetic risks of long-term waste management, when you get to that level of detail, then you can begin to end up with individual and specific projects.

For instance, in the case of health and genetic risks of long-term management, I can pull out of the file three projects: one by ERDA on radiation carcinogenesis in the amount of $96,000; one by EPA, looking at the postnatal development and function of the central nervous system in monkeys exposed to tritiated water; and another one by HEW, perhaps by Dr. Rall of the National Institute for Environmental Health Services on carcinogenesis by radiation plus estrogen.

The point I wish to make here is that by having outlined what the needs and requirements are in the fuel cycle one can begin to subtract from it the related ongoing work in the various agencies and find out totally what is going on and what particular areas it is going on in, which leaves the important information on what is not being done that should be done.

You might be interested in the fiscal 1976 budget, which is the last for which we have material.

The amount of biomedical and environmental research in the nuclear area going on in the Nation is more than $70 million.

The amount going on in the environmental technology area is $33 million plus.

In the operational safety area—and I categorize in that area one of the areas Mr. Gossick mentioned namely, the reactor safety research area—there is about $75 million.

The total research and development budget in the environmental health, safety, operational safety, and control technology aspects of nuclear energy is something on the order of about $200 million.

If you would like a number for comparison of the total amount being spent in the biomedical and environmental area as related to energy from all sources at the same time, it was about $450 million. So ERDA's nuclear research represents about half of what is going on in all agencies.

Let me discuss briefly two or three areas.

Clearly, we have taken advantage or tried to take advantage of all of the inadvertent exposures of humans to irradiation. The most massive study we conduct is that on the survivors of the atomic bombs in Japan. We are looking now at 109,000 people who were exposed more than 30 years ago, looking at the kinds of things that have happened to those people over this period of time.

Obviously, one of the early things that happened was that leukemia developed in those who had been exposed to a fairly high radiation level. Later on, cancer began to develop in the thyroid gland, in the breast, and the lung. Very clearly, from compelling evidence, the incidence of these cancers have been increased by the levels of radiation the people received.

Now, some 30 years later, there are suggestions, which we are continuing to try to confirm, that cancers may be developing in the salivary gland and in the stomach, at a higher incidence than in the normal aging population. That study is continuing with the Japanese Government splitting 50–50 on the costs.

We have also looked at the survivors, the Marshallese who were inadvertently exposed to fallout from tests in the Marshall Islands area.

There are people who, early on in this century and later, were injected with thorium or radium for medical purposes. We are following about 10,000 of these cases, principally through the work of the Argonne National Laboratory.

We have in being a transuranium registry where we are trying to keep a record on all of the people who have been exposed to plutonium and other transuranium elements, to look at what the health and environmental impacts—particularly health in this case—have been.

In addition, we started, about 2 years ago, a detailed study on plutonium epidemiology in people. There are about 16,000 people in that study, about half of whom have received some exposure to plutonium over the past 30 years.

Finally, we have a rather enormous study to look at all of the workers who have been exposed to radiation in any form other than plutonium or transuranium elements over the total life of the Atomic Energy-Manhattan Engineer District to try to see if we can detect through epidemiological studies what may have happened to those people.

That basically takes care of the discussion on the human health effects studies. Those studies in ERDA amount to about $12 million in fiscal 1978.

There are a lot of things, of course, that cannot be done with humans. One must address the question, then, in experimental animals and by other means.

The kind of questions one addresses, for example, are carcinogenesis, what are the exposure levels which cause cancer from neutrons, protons, gamma rays, and the heavy particles; looking at the dosimetry and the effects. It is particularly in this area that one can begin to link effects between the experimental animals of several different species and man to try to build the backlog of information and data, which will tie into the human studies for a baseline.

One looks also at the mutagenesis question. What are the levels of radiation which cause mutation? Does plutonium? Do other elements? Do they get into the animal chain so that you can get a far better understanding of the health effects research both in humans and in experimental animal systems?

Those kinds of studies amount to about $26 million per year in fiscal 1978 in ERDA.

It is pretty clear from research over the past 30 years that the environmental effects of radiation are fairly limited except insofar as the radioactive materials, particularly from fallout or from releases from accidents, may get into the food chain, which ultimately may lead to a body accumulation. Man then is exposed through his food supply; this was one of the concerns during the heavy fallout days of 1958, 1959, and 1960, principally strontium and iodine in milk.

The emphasis on the environmental studies in the nuclear area is to look at the food chain and the accumulation of those elements in fresh water, on land, and in the oceans. Those studies amount to about $12 million per year.

In addition, I mentioned earlier the necessity to develop the measurement techniques for all of these radioactive isotopes and they are quite different. There are more than 700 of them. You detect them all by the types of radiation they emit. My programs have been the ones in the Government that have done the most toward the development of the measurement techniques for plutonium and related substances. The physical and technological studies aimed at developing better instrumentation, better dosimetry calculations, and so on, amount to about $7 million per year.

There is another area of responsibility we have which has carried over from AEC under the Atomic Energy Act, looking at biomedical applications or the peaceful uses of the atom. That program has given rise, over the past 25 years, to the whole area of nuclear medicine. We in ERDA—previously the AEC—have supported the development of the techniques, the discovery and utilization, and in the early stages the evaluation of the isotopes. But the work is tied in very closely with HEW, Veterans' Administration, FDA and others to develop radio-pharmaceuticals for use and application to man. Basically there are really two programs, one to develop radioactive isotopes; the other to develop the medical devices such as the accelerators, which can be used directly for radiation therapy of people. We have joint programs with the National Cancer Institute, in particular, at most of our big machines, at Los Alamos, Berkeley, and Batavia, Ill., where patients are exposed to those heavy particles to try to treat specific diseases. Those programs amount to about $14 million per year.

That essentially sums up the activities that are carried out in the biomedical-environmental research area.

There are two other areas I would like to touch upon. One of them is the transportation area which you were discussing a few moments ago with Mr. Gossick.

It has been the ERDA program, and prior to that the AEC program, which has looked at the question of what is a suitable cask in which to transport nuclear materials safely.

We have done a sizable number of assessment studies, package failure modes, destructive testing of obsolete casks, contained structure response in accidents, and full-scale vehicle and container testing.

At the end of my testimony, if I could trouble the committee for 3 minutes, we have a very recent movie which shows field testing under realistic conditions that have had to do with the ability of these casks to undergo various kinds of accidents.

I think the film will be self-explanatory.

As you are aware, the Congress last year and the year before as riders on to our authorization and appropriations bill, required the NRC and ERDA to certify to the Joint Committee on Atomic Energy the safety of transportation of materials by air. NRC is currently leading that effort. We are providing information and R. & D. results to them. We have turned over to them the lead for putting together the appropriate package to come back to the Congress and certify the kinds of containers that would be safe.

In addition, we work jointly with DOT which regulates transportation and with NRC in all of these areas.

I would like to turn away from transportation and discuss, for a minute, some of the heritage the country has in the form of uranium mill tailings and the things that have happened to them over the years.

We had an unfortunate circumstance develop in Grand Junction, Colo., from mill tailings which were left there. Being rather fine sand and good foundation material, it turned out that about 300,000 tons of those tailings were removed from the millsite and put under houses, schools, and various buildings in Grand Junction, Colo.

About 5 years ago, 1972, the Congress passed a law directing the AEC to conduct a joint program with the State of Colorado to evaluate the nature of the problems resulting from this use of radioactive tailings, see what must be done, and to cure those problems with the Federal Government paying 75 percent of the cost and the State government 25 percent. We were authorized $5 million at that time and surveyed about 15,000 structures.

We have now surveyed about 4,000 more and covered all buildings constructed before 1966, when use of tailings was stopped. The estimate out of all those is that there are about 600 eligible for remedial action, which usually means removing tailings from underneath the house.

The problem, as you recognized earlier, is derived from radon gas from the radium, which itself is derived from the uranium. One of the things not removed when the uranium ore is milled to extract the valuable uranium is the radium. You have the same amount of radium present in the waste tailings as you did in the ore originally. You have pulled out nearly all of the uranium. What you end up with is a small amount of uranium plus lots of contamination, of which radium is the major culprit, in a large amount of finally crushed ground rock which has been converted into a mixture of fine sand and clay.

We expect to complete this program about 1980 at a total cost of about $8 million of the Federal Government's money, which would mean an additional $2 or $3 million from the State government.

That does not resolve the problem. There are in 8 Western States more than 22 abandoned mill tailings piles. One of the largest is in Salt Lake City. We are currently under direction from the Joint Committee, with the funding provided both by EPA and ERDA, to survey those 22 sites in the Western States to determine what it will require to clean up and stabilize those sites and to come back to the Congress for legislation. Our current estimate is that somewhere between $80 and $125 million is probably what will be required on the part of the Federal Government to go in and clean them up.

I mentioned the large pile in Salt Lake City. If you talk to Senator Garn, or prior to him, Senator Moss, you could get a very straightforward story about it. There are something, I believe, on the order of 2 million cubic yards of these materials. The cost could be anywhere from at little as $1 million to as much as $32 million. Since the States may have to put money in, it clearly will involve a lot of consideration on their part.

We have been having discussions with the Nuclear Regulatory Commission on this specific issue because we feel it is important to insure that in the future these situations are not walked away from, that provision is made for the cleanup of tailings piles and their stabilization or other disposition of them when a mill shutsdown before the license is terminated.

Let me mention one other area of responsibility which has to do with excess sites. During World War II, the Manhattan Engineer District operated in about 150 laboratories and small production facilities, besides those still in existence. They looked at sources of uranium from various kinds of ore, and to determine the best methods for extraction. These were all small efforts, fairly small efforts. It turns out in retrospect 30 years later, we probably did some things over a period of time that we now repent for; namely, we did not see to the adequate cleanup of a number of those places before they were turned back over to the public to be used. Currently, and under some prodding from the GAO beginning about 1½ years ago, ERDA began to pursue aggressively the survey of these 150 sites. One of the interesting things was that the documentation which would have shown what happened when they were turned back over to the public somehow or other mysteriously disappeared and does not exist. It may be in the Federal files in Atlanta or somewhere else, but you cannot get your hands on it. So it was necessary to go back and resurvey.

Now, to the 150 sites. We believe there are about 8 or 10 that probably are in excess of what would be permissible under current standards. Undoubtedly, we will have to go back in and work to clean up those sites. We do not believe that any of these constitute a current major health hazard, but nevertheless, we are pursuing aggressively the completion of that survey and will undoubtedly be back to the Congress with that question, too, as to how we best deal with it.

Let me mention one more activity after which I will stop and welcome whatever questions. It falls under my general purview to develop the criteria for cleanup of surplus contaminated facilities, like a reactor that might terminate its use, or like facilities in which radioactive materials have been used on ERDA sites. These are facilities ERDA owns. We are the ones charged with developing the techniques for decontamination, the techniques for dealing with it. There are a number of different methods. One could mothball. The reason for mothballing is because of the intense radioactivity which will decay to a point after about 100 years in which you could go in and clean the site up finally without elaborate and expensive shielding for the personnel. One could entomb it and come back again after a period of time. One could remove it and clean it up thoroughly. There are several other options.

We have gone through a number of these facilities. In fact, in my current budget, there is about $20 million a year that is devoted to that cleanup type of activity to finally bring this matter under control.

We are currently doing a very detailed excess facilities survey. I testified before Mr. Brown's subcommittee in the House about 10 days ago on the magnitude of the question that we are dealing with here. It looks like there will be, by the turn of this decade, something on the order of 1,000 facilities that have been at one time or another contaminated; and we do not have any real estimate of the cost, but it could be as much as $3 to $5 billion to clean up these sites and to bring them back to a state of being able to be used or released for general use.

If I can say now a few words about Federal coordination. Developing the inventory that I talked about requires an enormous amount of effort. There are about 25 or 30—it can vary from day to day—agencies in town working in the environmental and health areas as related to energy.

Therefore, it is absolutely essential that we work together as a group.

Furthermore, within that specific area, you will find that in general about four or five agencies will be concentrating in different areas of endeavor. In the health area, you will have heard today from most of the people that work in the health area as related to nuclear.

They are also the principal agencies that work in the health area as related to all energy sources.

The environmental area is another. It is a slightly larger group. Again it is six or eight agencies. You can go across the whole spectrum of characterizations made by monitoring. We have been deeply involved.

Furthermore, the President recently directed the Administrator of ERDA, the Secretary of HEW, and the Administrator of EPA to sit down and do an aggressive study on what are the health needs in the energy technology area that must be addressed. We have already set a meeting date to begin that discussion. We will work intensively then, not only nuclear but all of the technology areas in the health area.

I think it is likely that this will lead to a close working relationship in the environmental and all of the other areas in the immediate future also.

Mr. Gossick talked about the nuclear reactor safety research program. It turns out that within the ERDA complex, I am the one who is charged with seeing that the activities which NRC wants to conduct in ERDA facilities are carried out. So I carry in my budget about $20 million, in fiscal 1977, to move toward completion of the Loss of Fluid Test facility or the Idaho site. That is where work will be carried out by the Nuclear Regulatory Commission to test all of the computer codes to check for reactor safety.

I have mentioned in passing cooperative work with the National Cancer Institute, with the National Institute of Environmental Health Sciences, with EPA, and others. There is quite a bit of this work going on. We pass money back and forth between each other, depending upon the particular expertise of the agency to carry out the work, instead of reinventing the wheel and starting new laboratories.

With those comments, Mr. Chairman, if we could have the lights off and run this film?

Senator STEVENSON. Why don't we skip the film for now? I am afraid we are behind schedule, and we have to get on with the questions.

Dr. LIVERMAN. Fine.

Senator STEVENSON. That report will be entered in the record in full.

Is OMB trying to centralize all the research concerned with ionizing radiation in ERDA? We have been told that.

Dr. LIVERMAN. If so, I am not aware of it. I don't think that's true. Historically, we have had most of the R. & D. in ionizing radiation. The OMB did, with the help of EPA, and I think it is best to address the question to EPA, I believe 18 months or 2 years ago, say, ERDA is doing that, why does EPA need to do it?

That was a small amount of funding, a half to $2 million a year. We have had, in the last year, extensive discussions with EPA, going over the ERDA program from top to bottom, when they expressed interest in particular areas. They review our programs, and monitor them with us. They look at the research that results. That turns out to be a meaningful and truthful interaction.

Senator STEVENSON. One of the principal thrusts of the administration's energy program is to convert to coal, or to develop coal as a major source of energy. You described a process which includes the identification of concerns. Are we not to be concerned about radioactivity from coal-powered generating plants? What can you tell us about it?

Dr. LIVERMAN. It is quite clear to us, as Dr. Mattson from NRC said, that depending upon the amount of thorium or uranium or shale that is in the coal as it is mined and utilized, you can have varying amounts of not only radioactive materials but other toxic materials as well. Those are clearly of concern and must be dealt with.

It will vary, as you so rightly pointed out, not so much from the particular plant as from the coal itself and its source, where it came from. It is the amount of noncoal in the coal that largely determines that issue.

Senator STEVENSON. Can you be a little more specific? Can you tell us how much radioactivity is emitted into the atmosphere from the burning of different types of coal and how the administration's energy program intends to deal with that radioactivity?

Dr. LIVERMAN. I do not have that information with me, but I know that we are funding a program at the Mount Laboratory in which they are assessing the radiological impact of western coal utilization. The study has not been completed. Currently, it is believed that there is more radiation released from the burning of some coals than from nuclear reactors in commercial use. Those levels, however, are still fairly small and are not above the maximum permissible concentrations that one would allow, but it is not regulated at the present time.

Senator STEVENSON. Which coals are those? Where are they from?

Dr. LIVERMAN. I really don't know offhand. I think you would find some in West Virginia. You would undoubtedly find some in the Utah area where there is lots of uranium. That would be my guess offhand. I really don't know the precise origins.

Senator STEVENSON. Do you agree that there should be some standards and some regulation of coal to prevent unacceptable levels of radiation?

Dr. LIVERMAN. I certainly think one should look not only at the sulfur and related things, but also be acutely aware of the kinds of problems that could arise from radiation or from the other toxic materials, such as metals that could occur in the coal. It certainly is a question that needs to be addressed.

Senator STEVENSON. Is it a subject that has received adequate research?

Dr. LIVERMAN. The research that has been done is not adequate, in my view, in this particular area. It has never been of major concern because in preliminary examinations of a number of coals, it did not seem there was a problem of concern. But I think the question has to be addressed because the very fine particulates that do come out of coal-fired plants are exactly the right size, if you inhale deeply, to find their way into your lungs. It is also to these same particles that these toxic materials get bound.

So that question has to be dealt with. I question whether it is a major concern, but it needs to be addressed.

Senator STEVENSON. What is the current status of research on this question?

Dr. LIVERMAN. You mean levels of effort or some such thing?

I can probably pull that out of the summary sheet here. I do not know offhand those levels of effort. We are currently going through a very detailed analysis. We have outlined something on the order of 500 issues and requirements in the various technologies.

Let me see if I can put my finger on it right here.

In the coal area, total within the Government, in the areas we are talking about, there is a total of about $30 million; oil and gas an additional $30 million; oil shale about $5 million. Plus, in fossil in general, which is a little bit of everything, there is on the order of $90 million annually going into those areas related to fossil fuel combustion with $30 million of that in coal. Of that, there are about $7 million in the characterization, measurement, and monitoring area. A great deal of that money will have to do with the SO_x and NO_x research.

Our final report on the detailed analysis, to precisely the depth you are talking about, is due to come out in about 3 or 4 weeks. I don't think you want it for the record, but you certainly will want it for your committee's files. We will be happy to provide it to you.

Senator STEVENSON. Let's shift from burning of coal for a moment to the radiation from transmission lines. Is that a subject upon which you conduct research?

Dr. LIVERMAN. You mean high voltage transmission questions?

Senator STEVENSON. Yes.

Dr. LIVERMAN. We have some effort at a fairly low level. On the effects of magnetic fields that one deals with in the cryogenic transmission of electricity or fusion. In this case, we are addressing the effects of magnetic fields. The level of effort is probably on the order of $.5 to $2½ million a year in the total Government. We have on the order of $0.2 to a half million dollars.

Senator STEVENSON. What can you tell us about the dangers of exposure to radiation from transmission lines?

Dr. LIVERMAN. This is principally nonionizing radiation. I think there is nothing I could add to what Dr. Mattson already provided to you. If the intensity is enough, you could have neurophysiological effects. Obviously, if we go into microwave transmission, for example, if we had a solar platform in outer space and you send back solar energy to the Earth, it would be by microwave. That is a different question than the high voltage fields. But they are interrelated. Clearly, that effort will have to be increased considerably.

Senator STEVENSON. You mentioned mine mouths at one point in your testimony earlier. I didn't understand your reference to mine mouths.

Dr. LIVERMAN. I don't recall a specific reference to mine mouths. That might have been in reference to addressing the question of the fuel cycle from the time the material comes out of the mine, whether it is coal, whether it is uranium, or something else.

Senator STEVENSON. Are coal mines possible sources of radiation?

Dr. LIVERMAN. Well, they are not nearly as likely to be as uranium mines, because of the radium in the uranium. There may be some particular areas where it could be a problem, but methane and related things are more of a problem in coal mines than radium or radon.

Senator STEVENSON. Your statement indicated that atmospheric release advisory capability is being activated to provide better information about the dispersion of radioactive materials released accidentally from nuclear operation. What materials are released accidentally and how often does this occur and how serious is it?

Dr. LIVERMAN. It doesn't occur very often, but let's take the case of the Savannah River plant. Three years ago several hundred thousand curies of tritium, a radioactive gas, moved into the atmosphere. At that time, the concept of the atmospheric release advisory capability was tested. The advantage of ARAC, as we call it, is that we have studied the weather patterns, the movement of the atmosphere around those sites. We know the locations on a radial axis of where people are located, and where towns are located. Knowing, then, the wind velocity and direction, one can predict where the cloud of radioactive material would go and either move the people from there or, depending upon the situation, not be concerned about their health and safety. This is a technique which is now being instituted in all of our operating facilities and is being adopted by the NRC for its licensed plants as a predictive method on the direction which radioactive material, if accidentally released, would move.

Senator STEVENSON. You refer to a need for additional research to determine the effects produced by exposure to low levels of radiation. What is the status of research on that question, and more specifically, with respect to the assumption that any amount of ionizing radiation produces some deleterious effect?

Dr. LIVERMAN. The most conservative way to look at the effects of radiation is that there is no threshold below which there is no damage. In fact, the regulations of NRC and EPA, and others, are generally based on that straight-line function. Any radiation is bad. This is not totally proven, however. When you get down to the low levels, whether it be radiation, carcinogens, sound——

Senator STEVENSON. Nonionizing, as well?

Dr. LIVERMAN. Yes. When you get down to the very low levels, it is very difficult to differentiate a specific effect related to that pollution or insult, to separate the effect of that insult from the general environmental occurrence of cancer. These are the kind of end points you look at. It is very difficult. It is sort of the cigarette story all over, except in the case of cigarettes, you come up with a specific cancer that you can relate it to.

Because of the many different kinds of cancer that occur, one has to try to devise as accurately as possible many different kinds of systems that will measure effect at the lowest possible levels; then try to extrapolate from that to lower levels or to higher levels.

It is very easy to determine an effect at fairy high levels of radiation or carcinogens or mutagens. It is when you get to the low levels, which are the levels being regulated that it becomes important. It is obviously true that when you get into these areas, you run into lots of debate and argument.

The calculations that have been done on genetic effects, for instance, estimate that you would even experience some effects at 170 milliroentgens per year. If you tried to determine this precisely in experimental mice, it would take about 8 billion mice and probably 8,000 years.

In the meantime, evolution has taken place in the sea of radiation that man lives in. This seems to tell us that it is not a scientific question that is answerable.

Senator STEVENSON. We have been called for a vote now. Before I go, let me ask one question. Then we will have to follow up with written questions.

There's been a good deal of discussion about the neutron bomb. As I understand it, the warhead is designed to kill human beings via a high pulse of ionizing radiation, of about 8,000 to 10,000 rads. Any human exposed to this level of radiation would be killed. What do we know about the effects of the neutron warhead on humans who don't receive the lethal dose, who survive it, and on others? What is the effect on the environment and the long-term consequences for human beings?

Dr. LIVERMAN. Well, let's talk about the human question. Normally, if a population of 1,000 people received 500 roentgens of radiation half of them will die. If they receive less radiation than that, then the odds of their survival increase. At 100 roentgens or, maybe as much as 200 roentgens, the chances of survival are good. It is almost like a logarithmic curve as you get closer and closer to the 500 roentgens, whole body dose.

That really doesn't make much difference whether it is neutrons, protons, or gamma rays when you reach that level of dosage, except for those that do not penetrate, like beta alpha radiation. If the total body dose is penetrating radiation, which the neutrons clearly would be, because they have very high energy, then you can treat them all about the same. It will be lethal at the doses we are talking about.

At less than the lethal dose, one could develop leukemia. There are whole sequelae of things.

Senator STEVENSON. Presumably, some of the people exposed to this detonation would not receive a lethal dose. They would receive something short of it. Could it be lethal over a longer term?

Dr. LIVERMAN. You sort of repeat the story, then, of the 30 years of medical history we have collected on the survivors of the atomic bombs in Japan. Because of the very energetic nature of the neutrons here—in fact, one of the bombs released more neutrons than the other one—there are some data on that. I believe the Department of Defense probably at the Armed Forces Radiological Institute, AFRI, in Bethesda, probably has done experiments of the kind that provide more information. I am not personally aware of those.

Senator STEVENSON. Would the radioactivity that is released by detonation of such a bomb get into the environment and move?

Dr. LIVERMAN. The neutrons themselves, of course, decay very rapidly. If they induced radiation, it would turn out to be the same kind of radiation we would have from fallout or exposure of materials in a reactor. There would be some induced radiation that could get into the environment. I don't know the levels. We have not addressed this question directly.

Senator STEVENSON. You have not addressed it directly?

Dr. LIVERMAN. Not the question of the neutron bomb. My program has not addressed that.

Senator STEVENSON. Has anyone addressed it?

Dr. LIVERMAN. That I really don't know. I suspect that the Department of Defense at such places as the Armed Forces Radiological Institute has.

Senator STEVENSON. How far out from the point of warhead's impact is the level of 20 rads maintained?

Dr. LIVERMAN. I really don't know. This gets into weapons technology. There is certainly a well-documented history in a book that has been issued periodically on biological effects of nuclear weapons which has an enormous amount of background information in these particular areas. The book is Samuel Glasstone's "Effects of Nuclear Weapons."

Senator STEVENSON. Gentlemen, I have to go to the floor to vote. Thank you very much. We will follow up with written questions. The committee is recessed for as long as it takes me to vote.

[The statement and material referred to follows:]

STATEMENT OF DR. JAMES L. LIVERMAN, ASSISTANT ADMINISTRATOR FOR ENVIRONMENT AND SAFETY, U.S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

Mr. Chairman and members of the committee, I am pleased to appear before the Committee on Commerce, Science, and Transportation to discuss ERDA's research programs in the area of radiation health and safety research.

The House report on H.R. 6804 states that "an energy research and development program should not exist to serve its own ends, but to provide this country with the energy options which national priorities demand in order to balance our energy budget."

The President's energy plan has identified the use of light water reactors as an important source to help meet the Nation's energy requirements. Thus, it is anticipated that, for the near future, emphasis will be placed on overcoming the technological and environmental problems associated with light water nuclear reactors.

Because of the President's decision to defer indefinitely commercial reprocessing as well as use of any advanced reactor technology based on the use of separated plutonium, major emphasis in the nuclear area will be placed on the successful development of fusion and other advanced breeders and converter reactors, operating on fuel cycles which are less of a proliferation hazard. However, the continued production, fabrication, processing, transportation, and storage/burial of plutonium and other weapons grade materials for military purposes entail ERDA's continued commitment to health and safety research in this area.

While the present amount of information on the health effects of radiation and radioactive materials is extensive compared to that available for virtually any other industrial or environmetnal hazard, there are problems which still require additional attention. Concerns are particularly directed toward the potential biological effects of very low doses of radiation delivered at very low dose rates to large human populations and to the potential toxicity of plutonium and other alpha-emitting radionuclides. In addition, the potential bioenvironmental consequences of turning to an alternate fuel cycle, such as the thorium-uranium fuel cycle, require a continuing research emphasis.

To ensure the environmental acceptability of these technologies, I have instituted an environmental planning process which is structured to ensure the environmental acceptability of ERDA's energy technology programs from concept through R&D to the marketplace. The key component of this process is Environmental Development Plans (EPD's) which provide a guide for identifying, planning, and managing the environmental, health, and safety activities required by the energy technology programs. The EPD's are jointly prepared by my staff and the various energy technology staffs and specify environmental, health, and safety (EH&S) issues that must be addressed for each energy technology. For each issue, the research requirements that must be fulfilled to adequately address that issue are identified. In turn, research projects, assessments, or audits are defined and implemented. Thus, through this process, EH&S research activities are linked directly to the identified needs of the energy technology programs.

Our current knowledge of the interaction of radiation with living organisms spans every level of biological organization, from the molecular to human populations. Greater knowledge is needed to determine more accurately the movement of radionuclides, particularly actinides, through the atmosphere and the environment where man may be exposed. Occupational health programs emphasizing medical surveillance are also in progress. Research also remains to be carried out to determine the effects produced by exposure to low levels of radiation and biologically important radionuclides, especially plutonium and other transuranic nuclides, as well as studies of the biological and environmental factors which could modify the effects.

Much of this research is in my programs, specifically in the Division of Biomedical and Environmental Research (BER), the Division of Environmental Control Technology (ECT), and the Division of Operational and Environmental Safety (OES). The ongoing research programs fall into categories of human health, health effects involving other biological systems, environmental studies, supporting studies concerned with characterization, measurement, monitoring, and transport of radioactivity, and the transportation of nuclear materials.

We conduct research primarily to define and quantify the impact of energy technologies on human health. To accomplish this goal, we must first identify hazardous energy-related physical and chemical agents, so that adverse health effects induced by these hazardous agents can be identified and an understanding of the pathophysiological basis for such effects can be developed. In conjunction with this, we must develop methods for the early detection and diagnosis of energy-related health effects, and obtain quantitative data on dose-effect relationships in humans and animal species. Because human data are rare and hard to develop, the quantitative data derived from the different animal studies must be integrated into predictive models that can be used to estimate human health risks under a variety of exposure conditions. Finally, we must use this information to develop improved modes of protection and remedial actions.

The information gained from this research program provides the data needed to refine general human radiation exposure policies and standards. It also provides a foundation on which to base cost/risk/benefit analyses relative to health effects.

With regard to existing and developing nuclear technologies, we are concentrating our research to evaluate the health risks in several areas. Emphasis is given to exposures to low levels of external radiation or to radionuclides that might occur in work areas or in the general environment at particular stages of the nuclear energy cycle, particularly inhalation exposure because it is considered to have one of the most significant exposure potentials.

HUMAN HEALTH STUDIES

Whenever possible, data on potential health risks must be obtained from humans who have been exposed accidentally, occupationally, or medically to ionizing radiation. These data include information on the metabolism and deposition of radionuclides which is used as the basis for estimating the dose to organs that may be exposed to such materials. Because of the extreme importance of this program, it has received increased emphasis.

One of the best sources of this information is the Radiation Effects Research Foundation (RERF), formerly the Atomic Bomb Casualty Commission, which continues to study the effects from the nuclear weapons explosions on the Japanese exposed populations.

For example, firm evidence of an increased incidence of stomach cancer in Hiroshima survivors has been obtained recently, as well as presumptive evidence of an increased incidence of cancer of the esophagus, urinary tract, and lymphomas. No genetic effects have been established as yet. Biochemical studies are planned which will provide, potentially, a more sensitive means of detecting such effects compared to clinical observations.

Another study on the health of plutonium workers was started in 1952, with the periodic medical examination of 26 workers, exposed occupationally in 1944–45 at Los Alamos. A recent examination of these men revealed that, aside from physical changes compatible with aging, no evidence of disease associated with plutonium deposition was observed.

The U.S. Transuranium Registry (USTR), started in 1968 at the Hanford Environmental Health Foundation, serves as the national focal point for the accumulation of human data on the effects of exposure to plutonium and other transuranic elements. Its prime purpose is to correlate long-term effects of transuranic elements with actual tissue deposition in man.

Because most exposures occurred under occupational conditions, the Registry serves as a repository of all pertinent information, such as work histories, health physics data, and medical information. Participation is voluntarily obtained through acitve recruitment by the Registry which solicits cooperation from the workers to get both information from physicians and permission to obtain autopsy tissue specimens. To date, some 5,000 workers have been identified and registered. Of these, 3,900 have agreed to the release of medical records and 820 have authorized an autopsy by the USTR. Although 48 autopsies have been performed to date, the limited available data do not permit conclusions at this time.

The Los Alamos Scientific Laboratory greatly expanded its epidemiological research on plutonium workers approximately 3 years ago to include all known plutonium workers in the United States since the beginning of the nuclear industry in 1942. Data on morbidity and mortality as well as work histories are being collected both retrospectively and prospectively.

At the Argonne National Laboratory, studies of 3,100 persons, 1,900 still living, who were occupationally exposed to radium as radium dial painters or were given radium or thorium compounds in the course of medical procedures, are continuing to provide extremely important information on current permissible levels for long-lived alpha-emitting elements in man.

Also underway is a study which involves 4,500 former thorium workers identified from the employment records of an industrial plant where thorium ores were processed from 1935 to 1974. The hazards from thorium are of interest, not only because of its potential role in the nuclear fuel cycle, but also because thorium and plutonium seem to have similar effects in the lung.

Other human health programs include the study of persons in the Marshall Islands accidentally exposed to fallout from a hydrogen bomb after a weapons test in 1954 and the Health and Mortality Study, primarily of the Oak Ridge and Hanford worker populations. Expansion to include studies at additional facilities of interest is projected. With regard to all of these studies, the point that needs to be understood is that, because of the latency of radiation effects in humans, these studies are carried out over lifetimes. For this reason, any short-term information we receive is preliminary, at best.

HEALTH STUDIES IN BIOLOGICAL SYSTEMS

Because the data available for man are limited, controlled animal experimentation must be used to obtain detailed information about the kinetics and mechanisms of radionuclide metabolism. Animal studies also provide important quantitative and qualitative information about the effects of different exposure conditions and various modifying on dose-response relationships.

Since no mammal is a sufficient model for man, several species must be used and experimental conditions sought which make possible risk estimates for human populations. Using an interspecies comparative approach, insights are gained into species similarities and differences with respect to sensitivity to hazardous agents, patterns of response, metabolism of internal emitters, and organs at particular risk. The comparison of animal and human data makes it possible to determine for any given organ, hazardous agent, or set of exposure conditions, which animal species provide the most appropriate model for hazard evaluation in man. Such comparisons are used in developing predictive models applicable to human exposures. For examples, short-lived small animals, such as rodents, are useful in large-scale experiments designed to obtain statistically valid estimates of risk for low-dose exposures or for studying the influence of exposure conditions or other agents on observed effects. Long-lived large animals are used primarily to study the metabolism of various radionuclides and the pathophysiologic changes associated with diseases which only appear long after exposure.

Because biological systems, including man, plants, and animals, are more likely to be exposed to combinations of radionuclides and other hazardous agents, in addition to radiation, research in this area is being given high priority. Studies of low doses and dose rates are currently being emphasized because this is the type of exposure most likely to be encountered by the general public and few data are presently available. Thus, late effects, including life-shortening, mutations, cancer, and impairment of growth or development, are also prime research targets.

In order to be able to use this information to predict human health effects, an understanding is required of the processes involved in radiation damage to biological systems. It is necessary to study changes produced at the organ, cellular, and molecular levels to provide the understanding which permits interpretation of data from one system to another. Other studies are designed to improve methods for the early detection of abnormalities induced by hazardous agents. These include nuclear medicine techniques which help to define structural and functional changes of organ systems. One important effort is concerned with developing effective means of treating individuals exposed to internally-deposited transuranic radionuclides by the removal of the element through combining it with chemical agents.

ENVIRONMENTAL STUDIES

In the environmental area, it has been recognized for many years that the amount of radiation released from normal nuclear fuel cycle operations is not a limiting factor in terms of radiation effects on environmental biota. Thus, research activities on radiation-induced environmental effects are supported at a minimal level. The major emphasis of research in this area is on the physical and biological mechanisms involved in concentration, dispersal, remobilization, and transport of plutonium and other transuranic elements in and through various environmental media to man. These studies are being conducted in a variety of places where significant levels of radionuclides have been released, such as Rocky Flats; Miami, Ohio; Nevada Test Site; Greenland; the Marshall Islands; and in the Irish Sea, as well as in the general environment and in the laboratory.

An Atmospheric Release Advisory Capability (ARAC) is being activated to fill the need for better information on the dispersion, deposition, and dispersal of radioactive materials released accidentally from nuclear operations.

Since much is already known about the cycling and fate of the more common fission products on local, regional, and global scales from the surveillance and documentation of global distribution of fallout from nuclear testing programs, reseacch in these areas represents a smaller effort now than in past years.

CHARACTERIZATION, MEASUREMENT, AND MONITORING OF RADIOACTIVITY

In our research program to develop advanced radiation instrumentation and improved radiation dosimetry techniques, we are emphasizing the development of methods for measuring low-level plutonium and other transuranic elements. An interlaboratory comparison of *in vivo* plutonium measurement procedures is currently underway. Another major effort is focused on improving methods to determine low-level transuranics in soils. Other radiation dosimetry research activities, such as internal dosimetry research and neutron dosimetry development, are being supported. Our program is augmented by the application research programs of the Division of Operational and Environmental Safety, which includes such studies as the codification of good practices in plutonium facilities, the development of more accurate neutron dosimeters, and the formulation of guidelines for keeping radiation exposure "as low as practicable."

Extensive environmental monitoring is conducted at all of ERDA's major nuclear facilities and related studies are conducted to improve current knowledge of environmental transport mechanisms.

I will turn now to the research program in the Division of Environmental Control Technology and discuss the work supported by that Division to assure the safe transportation of radioactive materials.

TRANSPORTATION OF NUCLEAR MATERIALS

Radioactive materials are handled by the transportation industry in routine commerce on conventional transportation equipment. As a result, these shipments are subject to the normal transportation accidents. Protection of the public against the radiation hazard is achieved by a combination of package design, a limitation on the quantity and type of radioactivity authorized to be shipped in a specific package design, and radiation limitations external to the package.

The design criteria, quantity, and radiation limitations are set forth in the regulations of the Nuclear Regulatory Commission and the Department of Transportation.

Our research and development activities are designed to develop the data and methodology to evaluate the risk and environmental effects of shipping nuclear materials, and to support recommendations for new or modified transportation criteria. A draft tri-partite Memorandum of Understanding between ERDA, DOT, and NRC recognizes ERDA's expertise in the field of transportation of nuclear materials and provides for ERDA advice and consultation in the regulatory process.

Two principal areas of research efforts involve the assessments of the risks involved in transportation of various kinds of nuclear materials; and model and full-scale testing of containment systems to confirm the analytical and calculational techniques used in cask design. The results of these research activities are available to NRC and DOT for consideration in their regulatory rulemaking activities.

RESEARCH INTERFACE WITH REGULATORY AGENCIES

The data resulting from the many research programs are published in the open literature, in annual laboratory reports, in special symposium and workshop proceedings, and in special reports. Thus, research results are freely available to the national and international scientific communities.

However, we are attempting to channel this information more directly into the regulatory process, since much of the past and current radiation research is directly related and applicable to the needs of the regulatory agencies, particularly EPA and NRC. Last fall, ERDA and EPA held detailed discussions to examine and identify which of the ERDA studies in health effects, ecological processes, measurement technologies and development were in support of and applicable to the needs of EPA. As a result of these discussions, EPA has reexamined and revised its research needs and forwarded them to ERDA. These needs are being considered in the final preparation of the AES fiscal year 1979 budget.

Working relationships between ERDA and EPA are being formalized by a Memorandum of Understanding (MOU) which is currently being completed. The purpose of this MOU is to establish a policy of cooperation between the two agencies in the formulation and execution of Federal strategies, plans, and research programs to develop and use new energy sources and to effect conservation with full consideration to environmental consequences. The capabilities and resources of each agency will be used to the fullest extent possible to achieve this.

Under this MOU, standing ERDA/EPA committees will ensure that the following areas are adequately addressed:

(1) Policy Analysis and Environmental Guidance for Technology Development.

(2) Review and Control of Development, Demonstration, and Commercialization Projects.

(3) Environmental Research.

(4) Environmental Standards Development.

In this way we expect to have full interaction with EPA in applying our research to their needs, to make the results of that research available to them, and to jointly be aware of the need for regulatory actions so that new energy technologies may enter a commercialization phase in an environmentally acceptable manner.

Over the past 2 years, EPA has provided the AES approximately $900K of pass-thru funds to perform radiation surveys of uranium mill tailings sites in the Colorado Plateau and to conduct associated research and development efforts on measurement and remedial action techniques. Joint participation in the surveys and a continuous and open dialogue between ERDA and EPA staffs has led to mutually agreed upon research needs.

In other areas, interagency working groups have been established to provide an informal mechanism for exchange of information, access to laboratory expertise, as well as discussion of approaches, methodologies, and derivation of standards and Federal guidance.

There is, for example, an interagency working group chaired by the EPA on Federal guidance for transuranics in the environment. Participating agencies include ERDA, NRC, NASA, DOD, State, Commerce, Interior, and HEW. The scientific and technical basis for this guidance is primarily from present and past ERDA-supported research. Scientific data and appropriate ERDA laboratory personnel have been made available to EPA for their use.

In addition, an interagency working group has been established to assist EPA in the development of generally applicable environmental radiation protection standards for high-level radioactive waste. Participants include ERDA, NRC, and USGS. Again, ERDA technical, environmental, and biomedical information and access to appropriate laboratory experts, are being provided to EPA for their use as background information and for at least part of the technical basis for the development of the standard. Since the EPA did not have funds available for this activity, ERDA has agreed to provide $2 million for necessary EPA staff and contractor support.

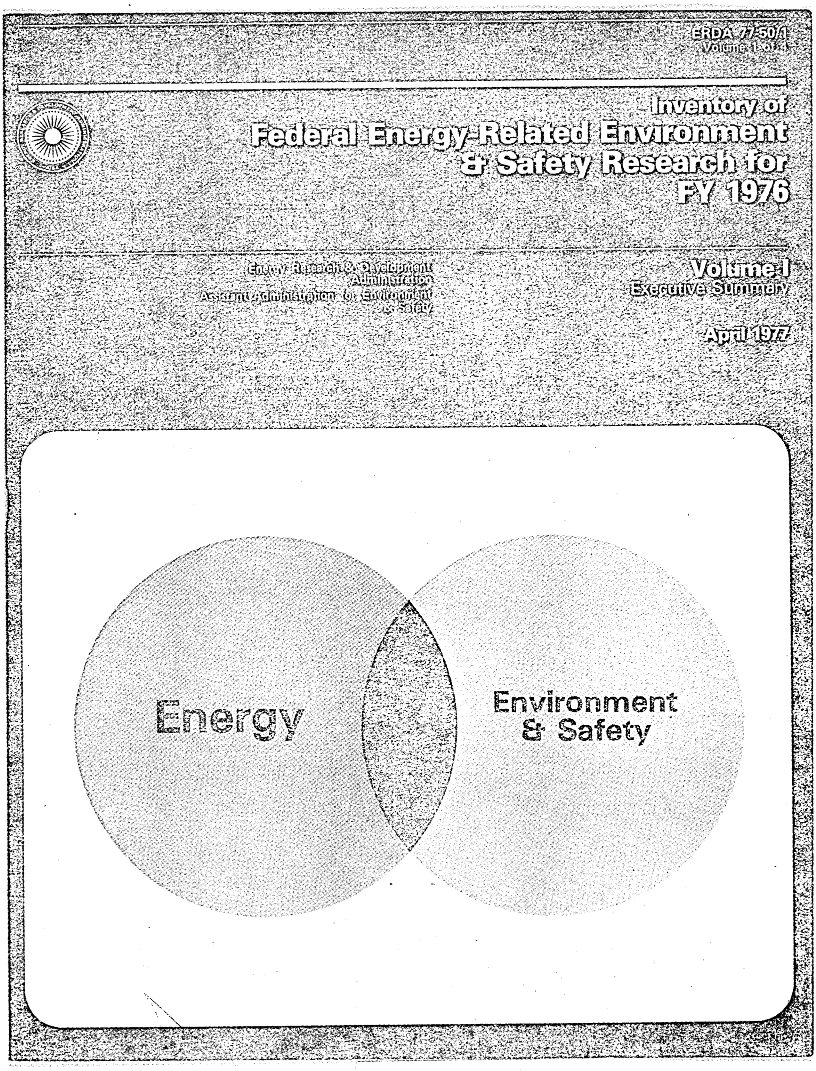
In addition, ERDA is reassessing the criteria for and consequences of land burial of low-level transuranic radioactive waste. In 1976, ERDA established an informal group to serve as a panel of experts on this activity. NRC, EPA, and CEQ were invited to attend these meetings. This study group is drawing heavily upon information generated by environmental and biomedical research supported by ERDA.

Frequent informal discussions are held with NRC regarding research needs related to their regulatory activities. These needs may be factored into ERDA's research activities; or, alternatively, NRC, through ERDA/NRC agreements, may wish to fund specific research at any of the ERDA laboratories.

In addition, ERDA radiation-related research has been used as a basis for a number of NRC documents, such as the Rasmussen Report and the Environmental Impact Statement for Generic Mixed Oxide Fuels.

In conclusion, Mr. Chairman, I believe that we have the research in place to address the most important radiation health and safety questions which have been identified. The objective of all our programs is to provide the knowledge necessary to develop nuclear technologies which can be implemented in a safe, clean, and environmentally acceptable manner. The EDP process is designed to help assure the identification of all issues and requirements associated with a technology from cradle to grave so that needed research programs can be developed and carried out. Although ERDA does not have responsibility for standards setting, an essential part of our responsibility is to work closely with the regulatory agencies to ensure that they have the necessary information to devise adequate criteria and standards. We are making every effort to do so.

This concludes my statement, Mr. Chairman. Thank you very much for this opportunity to discuss ERDA's radiation health and safety research programs. I will be happy to entertain any questions you might have.



ERDA 77-50/1
Volume 1 of 4

Inventory of Federal Energy-Related Environment & Safety Research for FY 1976

Energy Research & Development Administration
Assistant Administrator for Environment & Safety

Volume I
Executive Summary

April 1977

Energy
Environment & Safety

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Vol. 1 of 4
UC-11, 41, 66e

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Volume 1:

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April 1977

Prepared By:

The Aerospace Corporation

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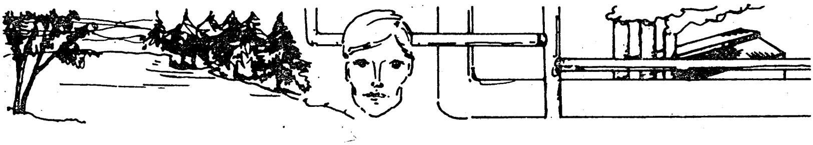
The Assistant Administrator for Environment and Safety,
Energy Research and Development Administration

Environment and Safety Group
Environment and Energy Conservation Division
THE AEROSPACE CORPORATION

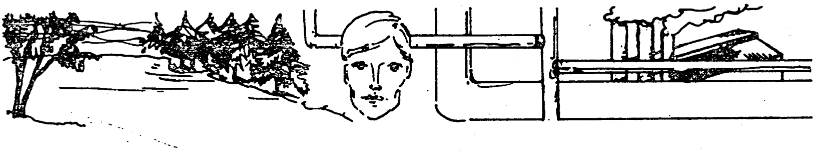


PREFACE

This Inventory provides an overview of federally funded energy-related environment and safety research projects for FY 1976. The catalog of the inventory data base is composed of an Executive Summary and three volumes of project listings for: 1) Biomedical and Environmental Research, 2) Environmental Control Technology Research, and 3) Operational Safety Research. The data contained in these volumes are an update of the FY 1974-1975 Inventory (ERDA-110) and represent research being conducted by the following agencies:

Department of Agriculture
Department of Commerce
Department of Defense
Department of Health, Education, and Welfare
Department of Housing and Urban Development
Department of the Interior
Department of Transportation
Environmental Protection Agency
Energy Research and Development Administration
Federal Energy Administration
National Aeronautics and Space Administration
National Science Foundation
Nuclear Regulatory Commission
Tennessee Valley Authority

The Executive Summary and all three catalog volumes of this inventory are available on request to the Assistant Administrator for Environment and Safety, Energy Research and Development Administration, Washington, D.C. 20545.



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The principal author and investigator was Mr. Thornton Blanchard, Jr., Environment and Energy Conservation Division, The Aerospace Corporation.

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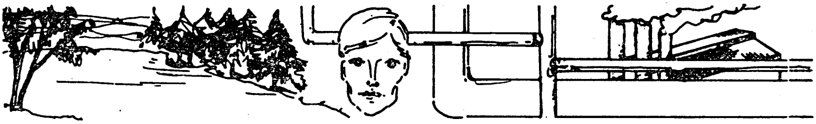

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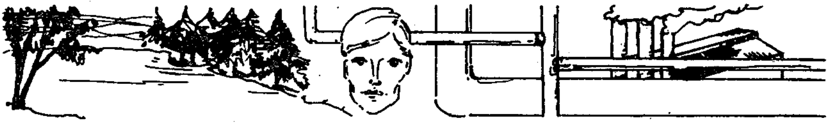


I INTRODUCTION

A. Purpose of the Inventory

The purpose of this Inventory is to provide a data base for providing overviews of federally funded, energy-related environment and safety research projects. The Inventory can be used to assist planning for future research by aiding in the determination of the adequacy of current environmental, health, and safety research programs to meet the needs of developing energy technologies.

B. Background

The Energy Reorganization Act of 1974, PL 93-438, authorizes the Administrator of the Energy Research and Development Administration (ERDA) to establish programs to minimize the adverse environmental effects of energy development and utilization. It further directs that these programs will utilize research and development efforts supported by other federal agencies in a cooperative manner to avoid unnecessary duplication.

In addition, the Federal Nonnuclear Energy Research and Development Act of 1974, PL 93-577, Section 6, requires that the Administrator of ERDA submit to Congress a comprehensive energy research, development, and demonstration plan and a companion comprehensive nonnuclear energy program on an annual basis. This annual report must include relative financial contributions by the agencies of the federal government.

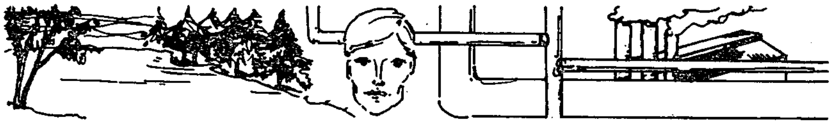
In order to comply with the requirements of these Acts, an initial inventory effort, the Federal Inventory of Energy-Related Biomedical and Environmental Research for FY 1974 and FY 1975 (ERDA-110) was published and distributed in October 1975.

The FY 1976 Inventory was improved by standardization and computerization of the data input. The requested information was expanded from the FY 1974-1975 Inventory of Biomedical and Environmental Research projects to include Environmental Control Technology and Operational Safety Research projects. A questionnaire was developed to obtain uniform descriptive material for the Inventory. Appendix A contains a copy of the questionnaire (OMB Form 294).

To obtain as complete an inventory as possible, all federal agencies likely to be involved in energy-related environment, health, and safety research programs were contacted. Questionnaires were distributed to seven federal departments (Agriculture, Commerce, Defense, Health, Education, and Welfare, Housing and Urban Development, Interior, and Transportation) and eight federal agencies or administrations (Environmental Protection Agency, Energy Research and Development Administration, Federal Energy Administration, National Science Foundation, National Aeronautics and Space Administration, Nuclear Regulatory Commission, Tennessee Valley Authority, and the U.S. Coast Guard).

C. Analysis

It is anticipated that ERDA will follow the publication of this Inventory with an analysis of the data contained within the Inventory. Publication of the ERDA analysis is not intended to preempt analysis of the data base by others. It is our hope that the Inventory data base will become a tool for use by state, regional, and federal planners and managers for analysis and program planning of research and development activities in the areas of energy, the environment, human health, and safety.



II INVENTORY SUMMARY

Presented herein is a summary of the distribution of research funding as determined from the FY 1976 Inventory of Federal Energy-Related Environment and Safety Research. This Inventory, although as complete as possible, is undoubtedly deficient in reporting all federally sponsored energy-related environment and safety research. It is often difficult for an agency to determine what research is energy related or to report relevant minor parts of larger projects that marginally fit the criteria for inclusion. With these limitations in mind, the information contained in the Inventory data base are summarized here and in the following three sections of the Executive Summary.

Fourteen federal agencies responded to the questionnaires to provide information for the Inventory. The data are limited to research conducted during FY 1976 and were reported individually by these agencies at the conclusion of that fiscal year. Table I presents the names of the agencies responding to the questionnaire, the number of projects each agency reported, and the FY 1976 funding level for research conducted by that agency in each of the three fields of interest: Biomedical and Environmental Research, Environmental Control Technology, and Operational Safety. Figure 1 shows the proportionate number of projects supported by each agency, and Figure 2 the percentage of the total reported FY 1976 expenditures by agency. It should be noted that the funding shown is that expended by the agencies conducting and/or contracting for the research, and is not necessarily the funding of the budgeting agency, although in most cases they are the same. Additionally, provision is made for funding by means of the EPA energy supplement (EPA "pass-thru"). When the agencies are ranked by dollar value of funding (as in Figure 2), it is of interest to note that about 84% of the total federal funding is represented by the sum of the budgets of the first four agencies (ERDA, NRC, EPA, and DOC).

The returns from the questionnaires have also been compiled and sorted to show the funds spent on environmental and safety research as a function of energy technology. Figure 3 shows this funding distribution. Fossil

TABLE I. Federal Agency Responses

Agency	No. of Projects Reported	Funding by Agency (in millions)
Department of Agriculture (DOA)	7	$ 7.6
Department of Commerce (DOC)	93	41.0
Department of Defense (DOD)	3	1.4
Department of Health, Education, and Welfare (HEW)	263	22.6
Department of Housing and Urban Development (HUD)	1	([a])
Department of the Interior (DOI)	80	25.9
Department of Transportation (DOT)	9	.4
Environmental Protection Agency (EPA)	305	63.0
Energy Research and Development Administration (ERDA)	1,467	197.5
Federal Energy Administration (FEA)	20	1.7
National Science Foundation (NSF)/RANN	18	1.2
National Aeronautics and Space Administration (NASA)	5	1.3
Nuclear Regulatory Commission (NRC)	200	77.5
Tennessee Valley Authority (TVA)	65	11.8
Total	2,536	452.9

[a] Less than $0.05M.

General projects are those that are fossil energy oriented but are not necessarily applicable to any specific fossil fuel technology. Nuclear General is the category for nuclear-oriented research projects that are not specifically applicable to either fission or fusion technologies. The Multitechnology category is used for projects that are related to four or more technologies. The General Science category relates to research that is supportive in nature and is not directly related to specific technologies. The "Other" category was provided for those energy-oriented projects that do not logically fall within any of the above categories.

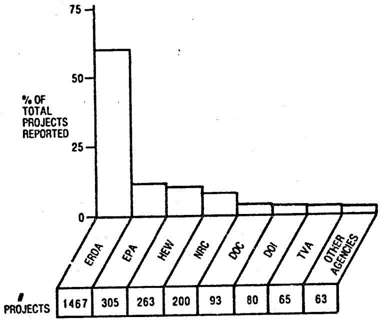


FIGURE 1. Number of Projects Reported by Each Federal Agency

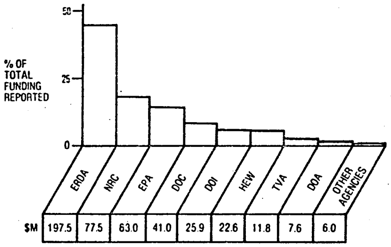


FIGURE 2. Research Funding Expended by Each Federal Agency

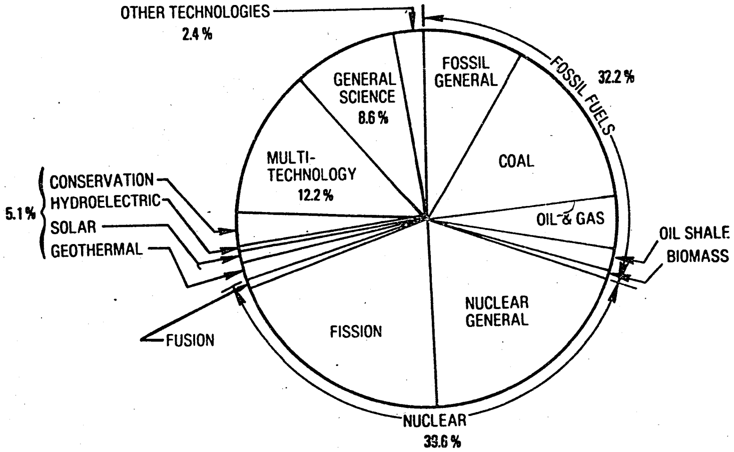


FIGURE 3. Distribution of Federal Funding by Energy Technology

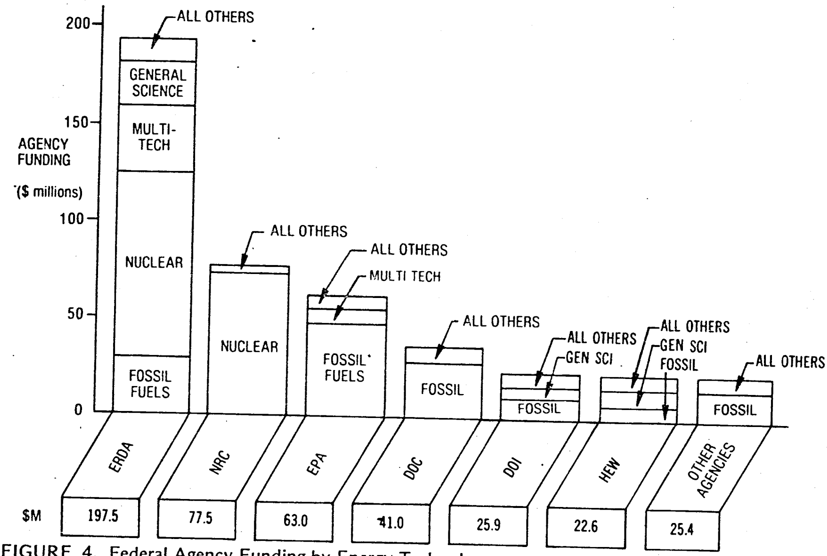


FIGURE 4. Federal Agency Funding by Energy Technology

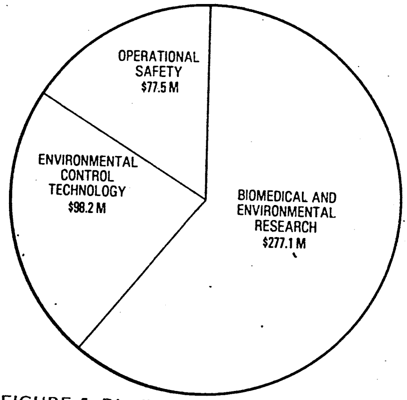


FIGURE 5. Distribution of Federal Funding by Research Category

The five agencies (ERDA, EPA, NRC, DOI, and HEW) that account for the major part of environment and operational safety research funding have been arranged in Figure 4 to show the relative emphasis placed by each of these agencies on energy technology areas. A more complete breakdown of energy technology fractions of each agency's program is shown in Table II.

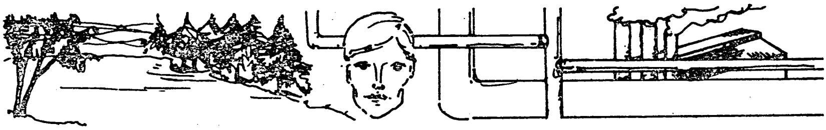
Funds for all agencies proportioned by major research categories—i.e., Biomedical and Environmental Research (BER), Environmental Control Technology (ECT), and Operational Safety (OS)—are shown in Figure 5. The next three sections of this report present a breakdown of the funds for these research categories.

TABLE II. Energy Technology Category Funding by Federal Agency, FY 1976

($ in millions)

Agency	Technology															Total
	Fossil General	Coal	Oil and Gas	Oil Shale	Bio-mass	Nuclear General	Fission	Fusion	Geo-thermal	Solar	Hydro-electric	Conser-vation	Multi-tech	General Science	Other	
DOA	4.7	2.1	-	0.6	-	0.2	-	-	-	-	-	-	-	-	-	7.6
DOC:																
OEA	-	-	-	-	-	-	-	-	-	-	-	0.2	-	-	-	0.2
NBS	0.4	([a])	-	-	-	0.7	0.3	([a])	-	-	-	-	0.7	-	-	2.1
NOAA	0.7	0.1	29.5	-	-	0.6	-	-	-	([a])	([a])	2.1	1.7	0.8	3.2	38.7
DOD	0.1	-	-	-	-	-	-	-	-	-	-	1.3	-	-	-	1.4
HEW:																
NIOSH	0.4	0.7	([a])	0.2	-	-	-	-	-	-	-	0.6	0.2	-	-	2.1
NIEHS	2.5	0.1	0.4	([a])	-	0.3	-	-	([a])	([a])	-	0.5	4.0	5.9	0.1	13.8
NCI	2.5	-	-	-	-	0.4	-	-	-	-	-	-	-	0.3	3.5	6.7
HUD	-	-	-	-	-	-	-	-	-	-	-	([a])	-	-	-	([a])
DOI:																
FWS	0.7	0.1	0.1	-	-	-	-	-	-	-	-	-	1.6	-	-	2.5
BLM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USGS	0.6	6.8	0.7	2.0	-	1.6	1.7	-	1.2	([a])	([a])	0.2	0.5	6.6	0.7	22.6
RECLAM	-	-	-	-	-	-	-	-	-	-	0.2	-	-	-	-	0.2
BPA	([a])	0.1	([a])	-	([a])	0.1	-	([a])	([a])	([a])	0.2	([a])	0.1	-	([a])	0.6
DOT	-	-	-	-	-	-	-	-	-	-	-	-	0.1	-	0.3	0.4
EPA	6.7	34.8	4.4	1.5	0.9	0.2	-	-	0.4	0.4	-	4.0	7.5	1.5	0.7	63.0
ERDA	9.7	15.1	3.4	2.4	([a])	60.6	34.7	2.1	2.8	4.6	0.2	1.9	35.6	22.4	2.0	197.5
FEA	0.3	0.1	([a])	0.1	-	([a])	-	-	([a])	([a])	-	1.0	-	-	([a])	1.7
NSF/RANN	0.4	0.2	([a])	-	-	-	-	-	0.3	0.1	-	-	([a])	0.1	([a])	1.2
NASA	0.2	0.4	-	0.1	-	-	-	-	([a])	-	-	-	0.5	-	-	1.3
NRC	-	-	-	-	-	7.9	66.5	-	-	-	-	-	2.2	0.9	-	77.5
TVA	1.3	7.2	-	-	-	0.9	0.2	-	-	-	0.2	0.7	0.5	0.3	0.5	11.8
Total	31.3	67.8	38.6	7.0	0.9	73.5	103.4	2.1	3.6	5.2	0.8	12.5	55.2	38.8	11.0	452.9

[a] Less than $0.05M.



III BIOMEDICAL AND ENVIRONMENTAL RESEARCH (BER) SUMMARY

The data discussed in Section II, Inventory Summary, are related to the total federal inventory and are presented to show the overall pattern of the funding/technology distribution by the various agencies involved. The following data are presented to show the distribution of research efforts in the field of Biomedical and Environmental Research (BER).

Presented in this section are data on those projects which were designated by the responders as being applicable, either entirely or in part, to the category of Biomedical and Environmental Research (BER). This category is further divided into five subcategories: 1) Characterization, Measurement, and Monitoring; 2) Environmental Transport, Physical and Chemical Processes and Effects; 3) Health Effects; 4) Ecological Processes and Effects; and 5) Integrated Assessment.*

Table III shows the distribution of each agency's fund for the fifteen individual energy technology categories** (twelve specific energy technologies, plus Multitechnology, General Science, and Other). Table IV presents the technology funding distribution for each of the five BER subcategories and Table V shows the subcategory funding for each federal agency.

Figure 6 presents the energy technology funding for the BER projects and shows that 34% of all BER funds were expended on R&D related to fossil fuel technology, 26% to nuclear, 18% to Multitechnology, and 13% to General Science. The balance of the funding is divided among the other technologies.

Figure 7 portrays the distribution of federal BER funds by each agency according to energy technology. The figure reveals that 87% of the funds are being spent by four agencies.

Figure 8 presents the distribution of agency funding by each of the five BER subcategories.

Comparison of the FY 1976 agency funding in the area of Biomedical and Environmental Research with that reported in FY 1975 (ERDA-110) shows that, although the total expenditures increased from $269 million in FY 1975 to $277 million in FY 1976, several exceptional differences in the data base should be noted.

The FY 1976 Inventory does not include projects from EPA's base program ($23.5 million for FY 1975); NSF's research directorate ($12 million for FY 1975); approximately $15 million from the BLM Outer Continental Shelf marine research program (approximately $25 million is indicated under NOAA) and $1.5 million from DOD.

The funding tables in this volume include all applicable ERDA expenditures; however, the descriptions of approximately 70 projects (totalling about 3.0 million) are not listed in the catalog. These projects are now being added to the computer data base at ERDA's Oak Ridge National Laboratory.

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*See Section II, Volume II, for subcategory descriptions.

**One of the energy technology categories listed on the questionnaire, Medical Applications of Nuclear Technology, is actually not supportive of energy technology and, therefore, has not been included in this listing.

TABLE III. Biomedical and Environmental Research Funding (Energy Technology by Federal Agency), FY 1976

($ in millions)

Agency	Technology															Total
	Fossil General	Coal	Oil and Gas	Oil Shale	Bio-mass	Nuclear General	Fission	Fusion	Geo-thermal	Solar	Hydro-electric	Conser-vation	Multi-tech	General Science	Other	
DOA	1.8	1.5	-	0.4	-	0.1	-	-	-	-	-	-	-	-	-	3.8
DOC:																
OEA	-	-	-	-	-	-	-	-	-	-	-	0.2	-	-	-	0.2
NBS	0.4	([a])	-	-	-	0.6	0.3	([a])	-	-	-	-	0.7	-	-	2.0
NOAA	0.7	0.1	29.3	-	-	0.6	-	-	-	-	([a])	1.8	1.7	0.8	3.2	38.3
DOD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HEW:																
NIOSH	0.3	0.6	([a])	0.2	-	-	-	-	-	-	-	0.5	0.2	-	-	1.9
NIEHS	2.5	0.1	0.4	([a])	-	0.3	-	-	([a])	([a])	-	0.5	3.9	5.9	0.1	13.8
NCI	2.5	-	-	-	-	0.4	-	-	-	-	-	-	-	0.3	3.5	6.7
HUD	-	-	-	-	-	-	-	-	-	-	-	([a])	-	-	-	([a])
DOI:																
FWS	0.7	0.1	0.1	-	-	-	-	-	-	-	-	-	1.6	-	-	2.5
BLM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USGS	0.5	4.0	0.2	1.7	-	1.6	1.0	-	1.2	([a])	([a])	([a])	0.5	6.2	0.6	17.8
RECLAM	-	-	-	-	-	-	-	-	-	-	0.2	-	-	-	-	0.2
BPA	([a])	0.1	([a])	-	([a])	0.1	-	([a])	([a])	([a])	0.1	([a])	0.1	-	([a])	0.4
DOT	-	-	-	-	-	-	-	-	-	-	-	-	0.1	-	-	0.1
EPA	3.2	7.1	1.1	0.7	([a])	0.2	-	-	([a])	-	-	1.3	4.4	1.0	-	19.1
ERDA	9.6	12.7	2.4	2.2	([a])	28.1	30.1	1.7	2.1	4.6	0.2	1.6	35.0	23.1	1.4	153.8
FEA	0.3	0.1	([a])	0.1	-	([a])	-	-	([a])	([a])	-	1.0	-	-	([a])	1.6
NSF/RANN	0.4	0.2	([a])	-	-	-	-	-	0.3	0.1	-	-	([a])	0.1	([a])	1.1
NASA	0.2	0.3	-	([a])	-	-	-	-	([a])	-	-	-	0.1	-	-	0.6
NRC	-	-	-	-	-	1.6	3.0	-	-	-	-	-	2.2	0.6	-	7.4
TVA	0.5	3.1	-	-	-	0.9	0.2	-	-	-	([a])	0.2	0.5	-	0.4	5.9
Total	23.7	30.1	33.6	5.4	0.1	34.5	34.6	1.7	3.6	4.7	0.6	7.2	51.0	37.0	9.3	277.1

[a] Less than $0.05M.

TABLE IV. Biomedical and Environmental Research Subcategory Funding by Energy Technology, FY 1976

($ in millions)

Energy Technology	BER Subcategory					Total
	Characterization, Measurement, and Monitoring	Environmental Transport	Health Effects	Ecological Effects	Integrated Assessment	
Fossil General	3.4	2.0	14.2	2.2	2.0	23.7
Coal	7.3	6.6	3.3	7.1	5.8	30.1
Oil and Gas	2.1	7.7	0.6	19.2	4.0	33.6
Oil Shale	1.9	0.8	0.8	0.8	1.2	5.4
Nuclear General	5.6	3.5	22.9	1.3	1.2	34.5
Fission	6.1	7.1	15.5	3.9	2.0	34.6
Fusion	0.2	0.1	0.9	(a)	0.5	1.7
Geothermal	2.7	0.3	0.2	0.1	0.2	3.6
Solar	(a)	(a)	3.2	1.0	0.5	4.7
Hydroelectric	0.2	(a)	-	0.2	0.2	0.6
Conservation	1.3	1.1	1.3	0.6	2.9	7.2
Multitech	10.4	10.3	11.7	11.3	7.3	51.0
General Science	2.0	1.7	25.8	4.3	3.1	37.0
Other	2.0	0.8	4.3	1.0	1.3	9.3
Total	45.1	42.1	104.8	52.9	32.1	277.1

[a] Less than $0.05M.

TABLE V. Biomedical and Environmental Research Subcategory Funding by Federal Agency, FY 1976

($ in millions)

Energy Technology	BER Subcategory					Total
	Characterization, Measurement, and Monitoring	Environmental Transport	Health Effects	Ecological Effects	Integrated Assessment	
DOA	0.3	0.8	-	1.8	0.9	3.8
DOC:						
OEA	-	-	-	-	0.2	0.2
NBS	1.9	([a])	0.1	([a])	-	2.0
NOAA	4.3	8.5	0.2	19.0	6.3	38.2
DOD	-	-	-	-	-	-
HEW:						
NIOSH	0.9	-	1.0	-	-	1.9
NIEHS	([a])	([a])	13.2	0.5	0.1	13.8
NCI	-	-	6.7	-	-	6.7
HUD	-	-	-	-	([a])	([a])
DOI:						
FWS	0.2	-	-	2.3	([a])	2.5
BLM	-	-	-	-	-	-
USGS	7.4	4.2	-	2.5	3.6	17.8
RECLAM	0.1	-	-	0.1	-	0.2
BPA	([a])	([a])	-	([a])	0.3	0.4
DOT	0.1	-	([a])	-	-	0.1
EPA	5.6	1.9	4.6	3.9	3.1	19.1
ERDA	20.8	21.3	78.4	19.6	13.7	153.8
FEA	0.2	0.1	([a])	0.2	1.1	1.6
NSF/RANN	0.2	0.3	([a])	0.3	0.2	1.1
NASA	0.2	0.2	([a])	0.1	0.1	0.6
NRC	1.6	3.5	0.6	0.7	1.0	7.4
TVA	1.2	1.3	([a])	1.9	1.5	5.9
Total	45.1	42.1	104.8	52.9	32.1	277.1

[a] Less than $0.05M.

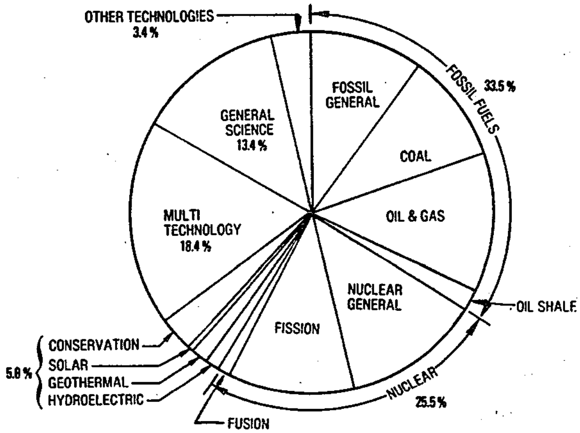


FIGURE 6. Distribution of Biomedical and Environmental Research Funding, by Energy Technology

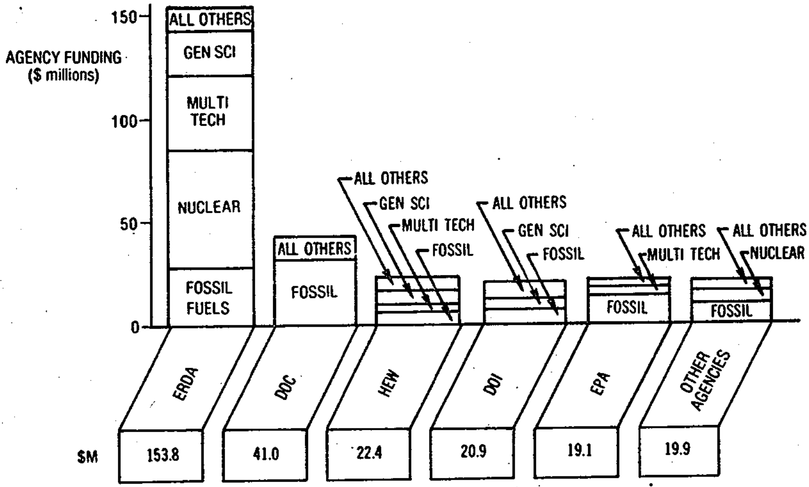


FIGURE 7. Federal Agency Biomedical and Environmental Research Funding, by Energy Technology

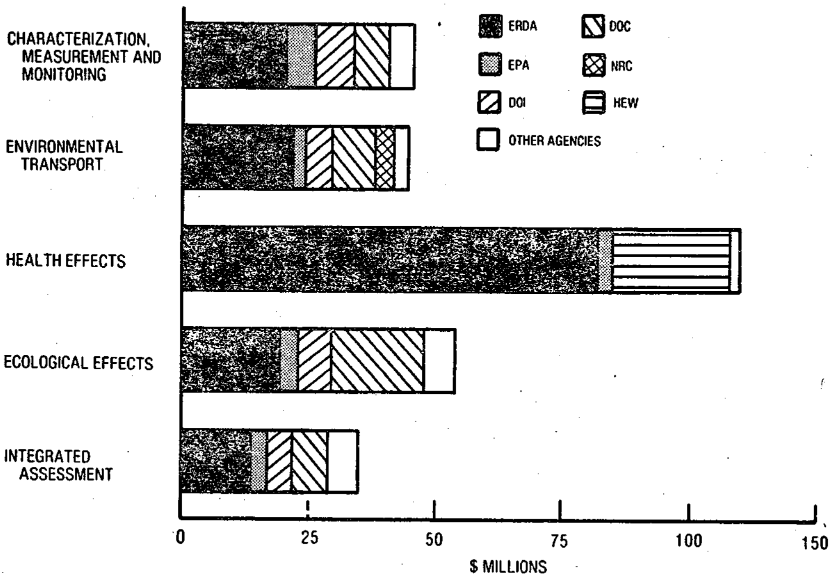
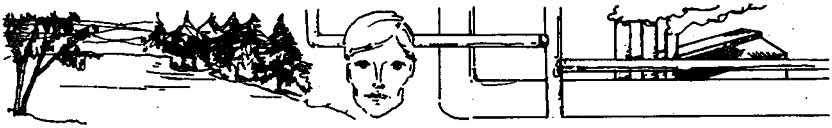


FIGURE 8. Distribution of Biomedical and Environmental Research Subcategory Funding, by Federal Agency



IV ENVIRONMENTAL CONTROL TECHNOLOGY (ECT) SUMMARY

Presented in this section are data on those projects which were designated by the responders as being applicable, either entirely or in part, to the category of Environmental Control Technology (ECT) research. Table VI shows the federal agency funds allocated to ECT for each of the fifteen* energy technology categories (twelve specific technology categories, plus Multitechnology, General Science, and Other).

Figure 9 presents the energy technology funding for the ECT projects and shows 53% associated with coal technology, and 34% with nuclear technology, and the balance of the funding divided between the remaining technologies.

Figure 10 portrays the distribution of funding by federal agencies, and shows the distribution of the agency ECT funds by energy technology. The data indicate that 82% of the funds are being spent by two (2) agencies, EPA and ERDA. From these data it can be seen that a significant portion of the EPA ECT funds are involved with fossil energies, while ERDA's funds are more directly applied to nuclear energies.

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*See Footnote (**), Section III.

TABLE VI. Environmental Control Technology Funding (Energy Technology by Federal Agency), FY 1976

($ in millions)

Agency	Technology															Total
	Fossil General	Coal	Oil and Gas	Oil Shale	Bio-mass	Nuclear General	Fission	Fusion	Geo-thermal	Solar	Hydro-electric	Conser-vation	Multi-tech	General Science	Other	
DOA	2.9	0.5	-	0.2	-	0.1	-	-	-	-	-	-	-	-	-	3.7
DOC:																
OEA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NBS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NOAA	-	-	0.1	-	-	-	-	-	-	([a])	([a])	([a])	-	-	-	0.2
DOD	0.1	-	-	-	-	-	-	-	-	-	-	1.3	-	-	-	1.4
HEW:																
NIOSH	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NIEHS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NCI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DOI:																
FWS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BLM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USGS	-	2.8	0.3	0.3	-	-	-	-	-	-	-	0.2	-	0.4	0.1	4.1
RECLAM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BPA	-	([a])	([a])	-	-	-	-	-	-	-	0.1	-	-	-	-	0.1
DOT	-	-	-	-	-	-	-	-	-	-	-	-	0.1	-	-	0.1
EPA	3.5	27.7	3.3	0.8	0.9	([a])	-	-	0.4	0.4	-	2.6	3.1	0.4	0.7	43.9
ERDA	0.1	2.4	1.1	0.1	-	30.5	0.7	0.2	0.7	([a])	-	0.3	0.5	0.2	0.2	36.9
FEA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NSF/RANN	-	-	-	-	-	-	-	-	-	-	-	-	-	-	([a])	([a])
NASA	-	0.2	-	([a])	-	-	-	-	([a])	-	-	-	0.4	-	-	0.7
NRC	-	-	-	-	-	1.3	([a])	-	-	-	-	-	-	-	-	1.3
TVA	0.8	4.0	-	-	-	-	-	-	-	-	0.1	0.5	-	0.3	([a])	5.7
Total	7.4	37.6	4.7	1.5	0.9	32.0	0.7	0.2	1.1	0.4	0.2	5.0	4.1	1.3	1.1	98.2

[a] Less than $0.05M.

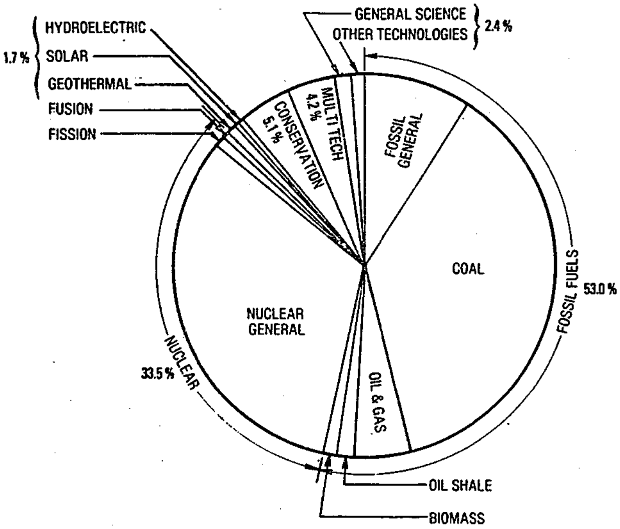


FIGURE 9. Environmental Control Technology Funding Distribution, by Energy Technology

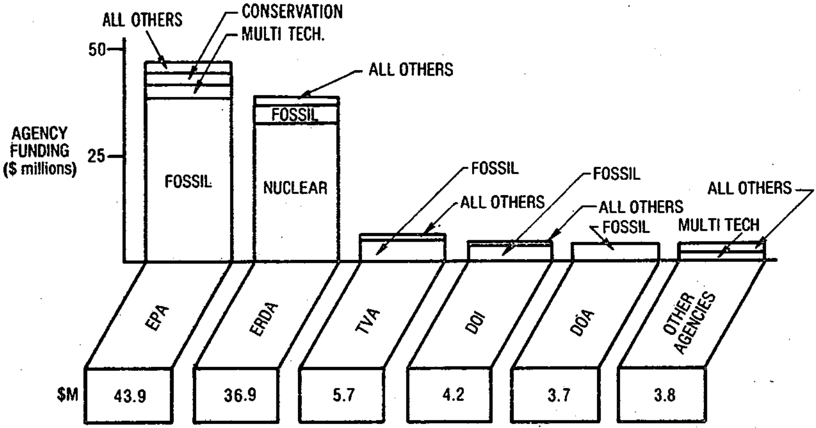
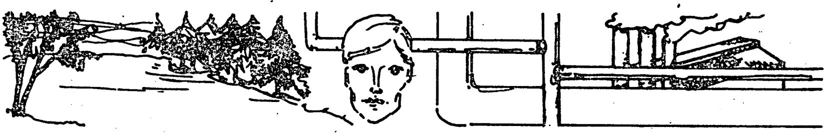


FIGURE 10. Federal Agency Environmental Control Technology Funding, by Energy Technology



V OPERATIONAL SAFETY (OS) SUMMARY

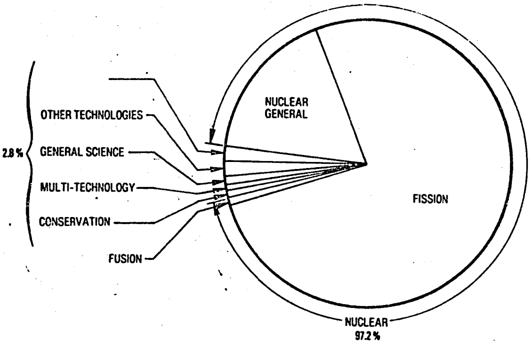


FIGURE 11. Operational Safety Funding Distribution, by Energy Technology

Presented in this section are data on those projects which were designated by the responders as being applicable, either entirely or in part, to the category of Operational Safety (OS) research. Table VII shows the federal agency funds allocated to the OS category for each of the fifteen* energy technology categories (twelve specific technologies, plus Multitechnology, General Science, and Other).

Figure 11 presents the energy technology funding for the OS projects and shows 97% associated with nuclear technology and the balance of the funding divided among the other technologies.

Figure 12 portrays the distribution of funding by federal agencies, and shows the distribution of the agency OS funds by energy technology. It is seen that 97% of the funds are being spent by two (2) agencies (88% by NRC and 9% by ERDA).

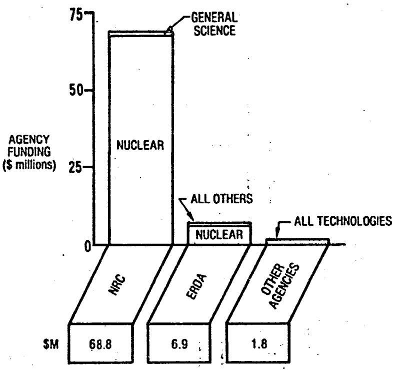


FIGURE 12. Federal Agency Operational Safety Funding, by Energy Technology

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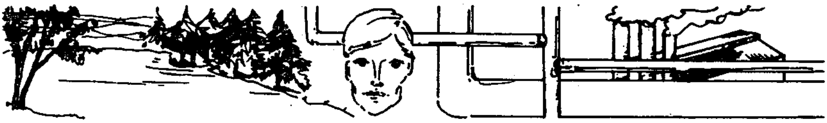
*See Footnote (**), Section III.

TABLE VII. Operational Safety Funding (Energy Technology by Federal Agency), FY 1976

($ in millions)

Agency	Technology															Total
	Fossil General	Coal	Oil and Gas	Oil Shale	Bio-mass	Nuclear General	Fission	Fusion	Geo-thermal	Solar	Hydro-electric	Conser-vation	Multi-tech	General Science	Other	
DOA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DOC:																
OEA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NBS	-	-	-	-	-	(a)	(a)	(a)	-	-	-	-	-	-	-	0.1
NOAA	-	(a)	-	-	-	-	-	-	-	-	-	0.3	-	-	-	0.3
DOD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HEW:																
NIOSH	0.1	0.2	-	-	-	-	-	-	-	-	-	(a)	-	-	-	0.3
NIEHS	-	-	-	-	-	-	-	-	-	-	-	-	(a)	-	-	(a)
NCI	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
HUD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DOI:																
FWS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BLM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
USGS	(a)	-	0.1	-	-	-	0.7	-	-	-	-	-	-	-	-	0.8
RECLAM	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
BPA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
DOT	-	-	-	-	-	-	-	-	-	-	-	-	-	-	0.3	0.3
EPA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
ERDA	0.1	(a)	-	-	-	2.0	4.0	0.2	-	(a)	-	(a)	0.2	(a)	0.3	6.9
FEA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NSF/RANN	-	-	-	-	-	-	-	-	-	-	-	-	-	(a)	-	(a)
NASA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
NRC	-	-	-	-	-	5.0	63.4	-	-	-	-	-	-	0.4	-	68.8
TVA	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total	0.2	0.2	0.2	-	-	7.0	68.1	0.2	-	(a)	-	0.4	0.2	0.4	0.6	77.5

[a] Less than $0.05M.



APPENDIX A INVENTORY QUESTIONNAIRE

FORM ERDA-294
(1-76)

FORM APPROVED
OMB NO.038-R0188

Inventory of Federal Energy-Related Environment and Safety Research

FY 1976

Energy Research and Development Administration
Office of the Assistant Administrator
for Environment and Safety

INSTRUCTIONS

for

Project Documentation

Energy-Related Environment and Safety Projects

For purposes of this Inventory, a project is defined as an investigation with a specific objective to be met within prescribed time and dollar limitations (normally planned on a fiscal year basis). It may be a theoretical or analytical study. It may be basic or applied research or development. It will generally be the lowest level or an agency's work breakdown structure. More detailed breakdowns of a work unit by a contractor are not generally considered to be a project. A contract may cover multiple projects, however, a project would not involve more than one contract.

SECTION I - ADMINISTRATIVE

Item 1	Please use full project title. Do not abbreviate.
Item 2	This will be the identification number of the responsible federal agency for both new and continuing projects. (In the case of ERDA projects, use the Research Project Identification System (RPIS) number, if known.)
Item 3	Date of completion of questionnaire.
Items 4 through 6	Self explanatory.
Item 7	If project is being performed in a foreign country, insert country's name under Item 7 - STATE.
Items 8 and 9	Self explanatory.
Item 10	FTS - Federal Telecommunications System
Item 11	Monitoring Agency is the federal agency responsible for interfacing with the contractor and directly monitoring the contracted work. (This may or may not be the funding agency)
Items 12 through 15	Self explanatory.
Item 16	In most cases, the Funding Agency is the same as the monitoring agency. If funding is received from more than one agency, please list each agency's funding separately.
Item 17	Enter scientific and technical manpower only; do not include management, secretarial, and administrative support (graphics, publishing, etc.).
Item 18	If current activity is a continuation of a previous project, the start date should indicate the initiation of the prior work. Thus, the duration should cover the time from the start of previous work to the expected completion date. If the project is a continuing activity with no set completion date, enter N/A for not applicable.

(Instructions are continued on inside back cover)

Form ERDA-294
(1-76)

INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT DOCUMENTATION - FY 1976

(Please print in black ink or type)

SECTION I - ADMINISTRATIVE

PROJECT TITLE

1. PROJECT TITLE

2. PROJECT NUMBER

3. DATE *(Day, month, year)*

PRINCIPAL INVESTIGATOR

4. NAME *(Last, first, initials)*

5. BUSINESS ADDRESS

6. CITY

7. STATE

8. ZIP

9. INVESTIGATOR'S AFFILIATION *(Full name)*

10. TELEPHONE (Area) ________ ○ FTS ○ Commercial

PROJECT MONITOR

11. MONITORING AGENCY(s) *(Full name)*

12. MONITORING AGENCY DIVISION OR OFFICE *(Full name)*

13. MONITOR'S PROJECT OFFICER *(Last, first, initials)*

14. TELEPHONE (Area) ________ ○ FTS ○ Commercial

PROJECT ACCOUNTING

15. TYPE OF FUNDING ACTIVITY *(Check one)*

a. ○ Contract No. ________

b. ○ Grant No. ________

c. ○ Agency in-house effort

d. ○ EPA "pass-thru" funding

e. ○ Interagency agreement ________ (funding agency)

16. FUNDING *($ thousands)*

Funding Agency(s)	FY 75	FY 76	Transition Quarter	FY 77	Funding Beyond FY 77 to Complete
a.	b. $	c. $	d. $	e. $	f. $
g.	h. $	i. $	j. $	k. $	l. $

17. SCIENTIFIC AND TECHNICAL MANPOWER *(Man Years)*

a. FY 75 ________

b. FY 76 ________

18. PROJECT SCHEDULE

a. Duration: ________ months

b. Start date: ________ (day, month, year)

c. Expected completion date (if not applicable, enter N/A) ________ (day, month, year)

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

SECTION IIA

GENERAL CATEGORIES
(Enter project percentages in applicable boxes and check applicable circles)

TECHNOLOGY

19. FOSSIL FUELS (including synfuel)
- a. ☐ Fossil Fuels (general)
- b. ☐ Coal
  - 1) ○ Conversion - Liquefaction
  - 2) ○ Conversion - Gasification
- c. ☐ Oil and Gas
- d. ☐ Oil Shale
- e. ☐ Biomass - pyrolysis

20. NUCLEAR
- a. ☐ Nuclear (general)
- b. ☐ Fission
  - 1) ○ Converters
  - 2) ○ Breeders
- c. ☐ Fusion
  - 1) ○ Magnetic
  - 2) ○ Laser

21. ☐ HYDROELECTRIC

22. GEOTHERMAL
- a. ☐ Geothermal (general)
- b. ☐ Hydrothermal
- c. ☐ Geopressurized
- d. ☐ Hot dry rock

23. SOLAR
- a. ☐ Solar (general)
- b. ☐ Direct heat/cool
- c. ☐ Electric
- d. ☐ Ocean, wind
- e. ☐ Biomass

24. CONSERVATION
- a. ☐ Conservation (general)
- b. ☐ End use
- c. ☐ Improved conversion efficiency
- d. ☐ Energy storage

25. ☐ MULTI-TECHNOLOGY

26. ☐ GENERAL (OR BASIC) SCIENCE

27. ☐ MEDICAL APPLICATIONS OF NUCLEAR TECH. (ERDA only)

28. ☐ OTHER ____________ (specify)

______
TOTAL to 100% (Items 19 through 28)

ENERGY CYCLE

29. ☐ Extraction

30. ☐ Combustion in situ

31. ☐ Transportation

32. ☐ Storage

33. ☐ Processing, Conversion

34. ☐ Combustion or End-use

35. ☐ Electricity generation

36. ☐ Electrical transmission

37. ☐ Waste management

38. ☐ Does not apply

______
TOTAL to 100% (items 29 through 38)

POLLUTANTS (specify)

39. ☐ Noxious gases ____________

40. ☐ Metals ____________

41. ☐ Particulates ____________

42. ☐ Organics ____________

43. ☐ Radiation ____________

44. ☐ Noise/Vibration ____________

45. ☐ Heat/Thermal ____________

46. ☐ Visual Aesthetics ____________

47. ☐ Other ____________

48. ☐ None

______
TOTAL to 100% (items 39 through 48)

CHARACTER OF STUDY

49. ☐ Research
- 1) ○ Theoretical
- 2) ○ Laboratory
- 3) ○ General
- 4) ○ Applied

50. ☐ Development
- 1) ○ Laboratory Scale
- 2) ○ Pilot Plant

51. ☐ Full Scale Demonstration

52. ☐ Production

53. ☐ Analytical/"Paper" Study)

______
TOTAL to 100% (items 49 through 53)

REGIONS OF INTEREST
(Check applicable circles)

54. Biomes
- a. ○ Atmospheric
- b. ○ Terrestrial
- c. ○ Freshwater
- d. ○ Estuarine
- e. ○ Marine
- f. ○ Does not apply

55. Geographic Areas
- a. ○ Northeast
- b. ○ Midwest
- c. ○ Southeast
- d. ○ Middle Atlantic
- e. ○ South
- f. ○ Southwest

56. (continued)
- g. ○ Far west
- h. ○ Northwest
- i. ○ Alaska
- j. ○ Continental
- k. ○ Global
- l. ○ Site specific ____________ (specify)
- m. ○ Does not apply

57. Coasts
- a. ○ Northeast
- b. ○ Southeast
- c. ○ Gulf

58. (continued)
- d. ○ Far west
- e. ○ Northwest
- f. ○ Alaska
- g. ○ Other ____________ (specify)
- h. ○ Does not apply

59. Hydrographic Areas
- a. ○ Deep ocean
- b. ○ Continental shelf
- c. ○ Great Lakes
- d. ○ Other ____________ (specify)
- e. ○ Does not apply

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

SECTION IIB BIOMEDICAL AND ENVIRONMENTAL RESEARCH CATEGORIES
(Enter project percentages in applicable boxes)

CHARACTERIZATION, MEASUREMENT, AND MONITORING

60. Characterization of source terms and pollutants
    - a. ☐ Baseline measurements
    - b. ☐ Operating site measurements
61. Measurement technology
    - a. ☐ Advanced concepts, components and systems
    - b. ☐ Applied systems
    - c. ☐ Quality assurance and standards
62. Monitoring
    - a. ☐ Occupational health
    - b. ☐ Public health

ENVIRONMENTAL TRANSPORT - PHYSICAL AND CHEMICAL PROCESSES AND EFFECTS

63. ☐ Environmental transport, dispersion and diffusion of pollutants (including modeling and geochemical cycling).
64. ☐ Physical and chemical transformation of pollutants (e.g., photochemical reactions in atmosphere, adsorption of pollutants by soil particles).
65. ☐ Processes by which pollutants are removed from air, land and water.
66. ☐ Pollutant effects on materials.
67. ☐ Terrestrial disturbances resulting from resource extraction (e.g., seismic activity, surface modification, aquifer disruption).
68. ☐ Meteorological/climatic effects of heat, moisture, and pollutant releases.

HEALTH EFFECTS

69. ☐ Screening for hazardous agents (toxicity, teratogens, carcinogens, etc.)
70. ☐ Determine disposition, metabolism, turnover, and elimination of hazardous agents.
71. ☐ Determine processes of damage, repair, recovery, protection, and amelioration.
72. Determine effects of energy-related pollutants on man
    - a. ☐ Epidemiological studies
    - b. ☐ Clinical studies
    - c. ☐ Biological dose-effect studies (non-human experimental research models).

ECOLOGICAL PROCESSES AND EFFECTS

73. ☐ Baseline measurements and determination of ecological parameters.
74. ☐ Ecological impacts related to physical disturbances (e.g., injection of waste heat, land disruption-reclamation, offshore drilling).
75. Ecological impacts related to chemical disturbances
    - a. ☐ Absorption and toxicity of pollutants
    - b. ☐ Cycling of pollutants in the biosphere
    - c. ☐ Biotransformation of pollutants.

INTEGRATED ASSESSMENT

76. ☐ Environmental Data Integration
77. ☐ Health Assessment Methodology (includes transport models)
78. ☐ Environmental Assessment Methodology (includes socio/economic and cultural implications, and regional coordination and case studies)
79. ☐ National/Regional Energy Technology Assessments
80. ☐ Environmental Policy Analysis

Total to 100% (Items 60 thru 80)

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

SECTION IIC ENVIRONMENTAL CONTROL TECHNOLOGY R&D CATEGORIES

(Enter project percentages in applicable boxes and check applicable circles)

Environmental Control

Development of procedures, processes, and systems which are designed to mitigate the environmental, health and safety impact of emissions and discharges and energy system wastes.

		81. Air Quality Controls	82. Solid Waste Management and Land Reclamation	83. Water Control and Protection	84. Other (Explain Below)
		☐	☐	☐	☐
a.	Integral to fuel cycle	○	○	○	○
b.	Add-on system	○	○	○	○
c.	Stationary source	○	○	○	○
d.	Mobile source	○	○	○	○
e.	State-of-the-art	○	○	○	○
f.	Extension to state-of-the-art	○	○	○	○
g.	Advanced system	○	○	○	○
h.	Not applicable	○	○	○	○

Other explanation ____

85. ☐ Disposal of surplus contaminated equipment and facilities.

Energy Materials Transport

86. ☐ Development of procedures, processes, and systems for the safe, secure, and operationally efficient handling, packaging, and transport of fuel cycle materials in accordance with environmental, health, and safety standards.

________ TOTAL to 100% (items 81 through 86)

SECTION IID OPERATIONAL SAFETY R&D CATEGORIES

(Enter project percentages in applicable boxes and check applicable circles)

87. ☐ Preparation and distribution of safety methods, standards, and regulations.
88. ☐ Evaluation and monitoring of plant and site operations and safety compliance.
89. ☐ Accident prevention programs, including training programs in health and safety.
90. ☐ Reactor safety programs, including decontamination and disposal.
91. ☐ Risk assessment
    1) ○ Data collection
    2) ○ Statistical data analysis
    3) ○ Accident investigation
92. ☐ Other safety programs ____ (specify)

________ TOTAL to 100% (items 87 through 92)

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

SECTION III **PROJECT DESCRIPTION**

93. PROJECT SUMMARY (200 words or less)

a. Objective:

b. Approach:

c. Product/Results Expected:

94. PROJECT MILESTONES

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

SECTION III PROJECT DESCRIPTION (continued)

95. KEY WORDS

In the Key Word List below, please circle up to six key words that best characterize your project. If the Key Word List is inadequate, provide up to three additional words which describe your project (maximum total six words). List and define additional words in space provided at bottom of this page.

Aerosols
Aging
Air
Animal
Bacteria
Biochemistry
Biomass
Biopsy
Blood
Bone
Cancer
Carcinogens
Cells
Climates
Computer Codes
Construction
Diseases
DNA
Economics
Ecosystem
Effluents
Electromagnetic
Element (Specify) ____________
Emissions
Enzymes
Epidemiology
Fate
Fauna
Fishes
Financial
Flora
Food

Forests
Gamma ray
Genetics
Glands
Heart
Hormones
Human
Hydrocarbon
Immunology
Ingestion
Inhalation
Instrumentation
Invertebrates
Infrared
In vitro
In vivo
Kidneys
Land
Lungs
Magnetic Fields
Medicine
Metabolism
Meteorology
Microwave
Mining
Molecular
Mutagenesis
Mutation
Neoplasms
Neurology
Nitrogen Compounds
Noise

Oil Spills
Oxidation
Pathogenesis
Photosynthesis
Plants
Plumes
Plutonium
Radionuclide
Reproduction
Respiration
RNA
Safety
Sewage
Scrubber
Sociology
Soils
Somatic
Subsidence
Sulfur Compounds
Synthetic Fuels
Teratogenesis
Thyroid
Tissues
Toxicology
Toxins
Ultraviolet
Virus
Waste
Water
Weather
X-ray

ADDITIONAL KEY WORDS AND DEFINITIONS

a) ____________ ____________________

b) ____________ ____________________

c) ____________ ____________________

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INVENTORY OF FEDERAL ENERGY-RELATED ENVIRONMENT AND SAFETY RESEARCH

PROJECT NUMBER ____________

ADDITIONAL INFORMATION

96. COMMENTS OR REMARKS

SECTION IIA - GENERAL PROJECT CATEGORIZATION

Items 19 through 28

Taking the whole scope of your project as 100%, estimate the percentage of the funding which applies to each of the numbered Technology Categories and write the percentage in the appropriate box. For those categories (such as Fossil Fuels) having further subcategorization (such as Conversion-Liquefaction), check in the appropriate circles. The sum of the percentages under Technology boxes should total to 100%.

The Multi-Technology box (item 25) should be used only if your project has a pervasive application or influence on all, or nearly all, technology areas. Examples: R&D on Instrumentation, Materials Research, Meteorological Research.

Insert a percentage figure in the General Science box (item 26) only if your project, or some portion, is basic in nature and not directly related to any specific energy technology.

Items 29 through 59

Proceed in a similar fashion to allocate a percentage of total effort being devoted to the various sequences of the ENERGY CYCLE (items 29 through 38), and also estimate the percentage applicable to the various POLLUTANTS (items 39 through 48). In each case, total to 100% as indicated. Under CHARACTER OF STUDY (items 49 through 53), the Analytical or "Paper" study (item 53) is defined as the compilation, evaluation, and/or synthesis of secondary data and information. These studies are not involved with the actual generation of original data. Under REGIONS OF INTEREST (items 54 through 59), check the applicable circles.

SECTIONS IIB, IIC, AND IID - ENVIRONMENT AND SAFETY CATEGORIES

Items 60 through 92

Complete Section IIB, IIC, or IID, whichever applies to your project. If you believe your project is applicable to more than one section, complete those sections. Enter estimated percentages in the appropriate boxes, check appropriate circles, and total each section to 100% as indicated.

SECTION III - PROJECT DESCRIPTION

Item 93

Enter a Project Summary (limit 200 words) covering the following:

Objective(s). State project objectives, quantifying where possible (e.g., "demonstrate 95% recovery of sulfur from raw gas with molten salt recycling at a rate of one gallon per minute").

Approach. Describe the technical approach to the project, i.e., how the work is to be done. (See Supplemental Instructions applicable only to Biomedical and Environmental Research projects.)

Expected Product/Results. Describe the final products or results expected from the project and their importance and relevance.

Item 94

A milestone is defined as a recognizable, project-important event that is expected to occur at a future point in time. An example might be "first launch of a fully instrumented balloon" or "interim report distributed." Milestones also include scheduled decision dates important to the design of an experiment or to the direction of research.

Item 95

Self explanatory.

SUPPLEMENTAL INSTRUCTIONS FOR SECTION III, ITEM 93

(APPLICABLE TO BIOMEDICAL AND ENVIRONMENTAL RESEARCH CATEGORIES)

Characterization, Measurement, and Monitoring

The requirements for information to be included in descriptions of projects under Characterization, Measurement, and Monitoring are very sensitive to the subcategory involved. If a project is directed toward the Characterization of Source Terms and Pollutants, the description should provide information of the instrumentation, the range, type, and number of measurements involved in the characterization of elemental, molecular, and particulate species, as well as the efforts being made to describe such agents as radiation, pressure, temperature, and electromagnetic fields.

If the project is in the Measurement Technology area, the description should indicate whether the project is intended to explore new and advanced approaches for pollutant detection, specification and measurement, or to develop specific measurement systems. In the latter instance the specific pollutant and the method of detection should be identified.

In the Monitoring area, descriptions should be provided of advanced strategies, techniques, and procedures for quantifying estimates of both occupational and general population exposure to energy-related pollutants.

Environmental Transport - Physical and Chemical Processes and Effects

Descriptions for projects in these areas should describe the design of the experiment, including such items as the pollutants involved, concentration and duration of exposure to toxic agents or pollutants, test organisms, methods of measurement, and environmental characteristics of test sites (if applicable).

Health Effects

The experimental design should be described, including:

a) test system(s): in vivo (species); in vitro (cell(s), organs, etc.)

b) exposure conditions: identity of chemical, biological or physical agents where pertinent, route of administration, dose and duration of exposure; acute, chronic, intermittent (cite time regimens)

c) biological endpoints to be assessed: metabolic, physiologic or pathologic changes, target organ, cellular or molecular species, developmental, mutagenic or carcinogenic effects.

Ecological Processes and Effects

See instructions for Environmental Transport - Physical and Chemical Processes and Effects.

Integrated Assessments

State issues of problems to be solved. Give results where possible. Where alternatives are developed, specify them. State technologies to which the project is related. For case studies, suggest possible wider application and do the same for any methodology developed.

Where models or data bases are used, they should be identified. Relation to other assessments should be stated, particularly if done by other agencies, or if aggregation or disaggregation is involved in which other assessments are used. Specific sites should be identified, as should states, river basins, mountain ranges or valleys, etc., where project work was done. If results of assessments are being used by state or regional commissions, offices, etc., or are directed toward their use, describe such use. Indicate relation to, or impact on, policy.

[The following information was subsequently received for the record:]

DEPARTMENT OF ENERGY,
Washington, D.C., October 11, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation,
U.S. Senate.

DEAR MR. CHAIRMAN: Thank you for your letter indicating that my testimony on June 28, 1977, at the oversight hearings on radiation health and safety was informative.

In response to your quest for additional information, I am enclosing:

1. Four publications requested by your Question No. 1.
2. Responses to the other 24 Questions.

If you should need more information, you need only call upon me.

Sincerely,

JAMES L. LIVERMAN,
Acting Assistant Secretary for Environment.

Enclosures.

Question. Please submit to the Committee 4 copies of the following materials:

A summary of the inventory of all environmental health and safety research relating to technologies developed by ERDA (cited on page 396 of the hearing transcript).

A status report on the ERDA, HEW, EPA interagency working group organized to study the health needs which are emerging as a result of new energy technologies.

Analyses of the radioactivity contained in major types of coal used in the U.S.[1]

Question. Various plans have ben proposed for the removal of nuclear wastes from the biosphere, primarily the use of deep geologic repositories and the Retrievable Surface Storage Facilities. Is there scientific evidence that either of these methods provides a safe and effective way of disposing of nuclear wastes?

Answer. The evidence for the safety of retrievable surface storage facilities and deep geological repositories for the removal of commercial nuclear wastes from the biosphere is based on nuclear industry experience and geological data, respectively. Years of experience with water basins for the storage of spent nuclear fuel along with experimental tests of dry storage casks provides ample evidence that the risk from monitored retrievable surface storage facilities will not significantly increase the risks to man from naturally-occurring disruptive events. However, the use of deep geological repositories will reduce significantly the need for monitoring. In this case, the risk to man from the many hazardous materials in the earth's crust will not be significantly increased by the return of the nuclear waste to deep geological repositories in the earth's crust.

Question. Is ERDA following through with these plans?

Answer. The ERDA program for commercial nuclear waste management does include the development of both retrievable surface storage and deep geological respositories for operation in the mid-1980's. Retrievable surface storage facilities are being developed for interim storage of spent nuclear fuel pending the resolution of the proliferation concerns regarding fuel recycle. Deep geological repositories are being developed for retrievable storage of spent fuel or for the terminal isolation of recycle wastes.

Question. Are alternative methods of waste disposal being considered?

Answer. The alternative waste disposal methods being given limited consideration are seabed, space, and transmutation. The seabed method offers an attractive alternative to deep geological repositories, particularly for countries without the geologic options. However, both the space and transmutation methods would only reduce the quantities of radioactivity going to terrestrial disposal and fuel reprocessing would be required.

Question. How much money is ERDA spending on nuclear waste disposal?

Answer. See table.

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[1] The materials were received and placed in the committee files.

[In millions of dollars; fiscal years]

Activity	Budget (BO)	
	Plan, 1977	Proposed, 1978
Commercial waste disposal:		
Terminal storage (deep geological)	30.2	68.0
Seabed	1.0	2.8
Transmutation	1.8	1.4
Space [1]	(.4)	(.4)
ERDA total	33.0	72.2

[1] Funded by NASA and not included in the total.

Question. Since 1972, 600,000 gallons of high level radioactive wastes have been stored at the now-defunct West Valley nuclear reprocessing plant in upstate New York. According to the General Accounting Office, the tanks are unsafe. The life of a tank is unpredictable; seismic criteria for the tanks are not being met, increasing the risk of rupture due to earthquakes; the value in which the tanks are being stored may float, as it has before, again increasing the possibility of serious releases. Furthermore, the State of New York and the Federal Government must decide who has the responsibility for the site, the waste itself must be analyzed, the techniques for tank removal must be investigated, and the future use of the site must be determined. How much money has ERDA budgeted to work on these issues? At your present levels of funding and manpower, how soon do you expect that West Valley will be cleaned up?

Answer. Continued surveillance of the West Valley storage tanks has shown no sign of presenting an immediate or near-term hazard to the public. At present cooperative efforts among NFS, NRC, and ERDA are underway to develop and apply increasingly sophisticated methods for analyses of the condition of the tanks to assure an early warning of any threat to the integrity of the tanks to store the waste. Even so a vault is provided which surrounds each tank with specifically designed devices and equipment to detect and handle leaks from the tanks. NRC has concluded that the properties of the soil, impervious silty till, provide additional protection to the tanks and their surrounding vaults.

Regarding the predictability of tank life, means do not now exist for predicting a precise time and date for failure of a tank, such as those at NFS. However, it may be noted that design life of the carbon steel storage tanks is 50 years and, based on the latest corrosion rate estimate at NFS (September 1976) using corrosion coupons in the tank, the serviceable life of the tank could exceed 100 years.

As to the extent of any risk to the tanks due to a seismic occurrence, the NRC currently is conducting studies to estimate that risk. We have been advised that the initial estimates are expected to be available within the next several months.

With respect to the possibility that the tank vault may float, although that occurrence did take place before the NFS facilities were completed and operated, it should be recognized that the tanks were then empty, and didn't have an overlaying weight of soil as is presently the case. Now, with the weight of stored liquid wastes plus the overburden to hold the vault in place, vault flotation does not appear to be a reasonable possibility.

The overall composition of the waste in the tanks has been established based on the characteristics of the fuels processed, and processing techniques, in the NFS facility. The supernate is sampled and analyzed regularly; the exact nature of the sludge is not now known. Sampling techniques and waste removal techniques developed at ERDA might be used or modified for use at West Valley if the waste is to be removed from the tanks. To our knowledge, a decision has not been made on whether the tanks themselves are to be removed from the site.

On the matter of responsibility for the site, current contractual arrangements involving the West Valley reprocessing facilities are primarily among NFS, New York State, and several private uiltities. They do not contemplate any financial liability on the part of the Federal Government for resolution of the situation now existing at West Valley. Thus, ERDA did not request any specific FY 1978 funds for that purpose, however, the FY 1978 Authorization Bill awaiting final approval contains $1.0 million for additional studies. Should it be determined in the future that Federal assistance or ownership will be required, the situation will, of course, change and the Federal funding will have to be provided. The ultimate resolution of the situation at West Valley can be expected to be time-consuming and complex. It is quite difficult to estimate a time at which this resolution may take place, and, as of now, we have not made such an estimate.

Question. The West Valley waste situation is not the only potentially hazardous one; 70 million gallons of similar high level wastes are being stored at ERDA installations such as Hanford, Savannah River and Idaho Falls. According to *Science* (February 18, 1977), "Leakage of waste from some of the tanks at both Hanford and Savannah River has been a persistent problem . . . nearly 500,000 gallons of waste have leaked from the tanks. . . ." Does ERDA have significant evidence that shows that this leakage does not pose a significant threat to public health?

Answer. Leakage of radioactive waste in the liquid form from waste storage tanks has occurred in the past, primarily at Hanford. The last leakage occurred in 1975. Varying amounts of waste totaling less than 460,000 gallons has leaked from 20 of the 149 older single-wall tanks at Hanford. At Savannah River, less than 100 gallons of radioactive liquid waste escaped from one waste tank. No waste tanks at the Idaho Chemical Processing Plant have leaked.

Each instance of waste leakage has been investigated and the extent that the liquid waste and the contained radioactivity moved from the buried tanks' walls determined. At Hanford, it has been found that the liquid waste and the radioactivity are immobilized by the dry sediments well above the regional water table with enough sediments above the contaminated zone to shield man from the radiation. At Savannah River, some of the radioactivity was recovered by pumping water from the ground, and the remainder (primarily cesium-137) has been retained by the sediments near the tank wall and is effectively isolated from contact with man. The tanks and contaminated soil are miles from areas where the public could be exposed.

Question. How much money and manpower has been spent or allocated to exaluating the dangers of tank leakage to man or to other forms of life?

Answer. The evaluation of potential dangers to man and other life forms consists primarily of the type of investigations mentioned above and continued surveillance of the contaminated zones to assure that the radioactivity is not moving. The surveillance of the contaminated zones is a minor part of an overall surveillance and maintenance function which also includes monitoring all waste tanks to assure prompt detection and remedial action in the event of another leak. Also, the liquid waste is being converted to less mobile solid forms to minimize future leakage. Total funding for the above programs in fiscal year 1977 was about $52 million and involved about 1,500 man-years of effort. A detailed tabulation is provided in Table 1.

Question. How much money and manpower has been spent or allocated to control the leakage of radioactive waste?

Answer. Improved waste storage tanks (tank-within-a-tank) are being built at Hanford and Savannah River for storing and handling waste in the liquid form prior to conversion to solid form. Total estimated cost for the improved tanks which have been constructed, or are either under construction, and/or planned is approximately $315 million.

The surveillance and maintenance and waste solidification programs and the construction of improved waste all are directed toward minimizing and the eventual elimination of leakage of stored liquid high-level radioactive waste.

TABLE 1.—FISCAL YEAR 1977 TOTAL FUNDING FOR RADIOACTIVE DEFENSE WASTE MANAGEMENT

[Dollars in thousands]

Site	Budget outlay	Man-years
Surveillance and maintenance:		
SR	$4,815	139
RL	7,965	238
ID	330	7
Total	13,110	384
Other waste management high-level:		
SR:		
Waste concentration	4,350	127
Waste tank evaluation	1,480	43
Total	5,830	170
RL:		
Waste concentration	8,880	258
Waste fractionization	13,420	387
Encapsulation	5,165	164
Startup/shutdown/standby	430	13
Total	27,895	822
ID: Solidification	5,210	110
Total	38,935	1,102
Grand total	52,040	1,486

Question. The former AEC was severely criticized in the past for failing to control the dispersion of uranium mill tailings at various sites in the Colorado Plateau. What actual health problems have arisen from the use of radioactive tailings?

Answer. To our knowledge, there are no cases of illness that could be specifically attributed to the use of radioactive tailings. Our concern derives, in part, from the large number of cancer cases that have developed among uranium miners who are subjected to the same type of radiation exposure as are persons living in structures built on tailings. However, the radiation levels in the mines are substantially higher than in most structures involving tailings. From 1954 through 1976, a total of 261 deaths from lung cancer, for which we have histological tissue confirming the cause of death, have occurred in the uranium miner population.

Extrapolating the exposure versus cancer incidence data to the levels of radiation found in structures built with tailings gives rise to concern that a potential health problem exists.

Question. What is the status of ERDA's current effort to stabilize and control these sites?

Answer. ERDA is providing 75 percent of the cost of a remedial program conducted by the State of Colorado for corrective action and structures in Grand Junction, Colorado, to reduce radiation exposures resulting from use of radioactive tailings as a construction material. The work commenced in FY 1973. Through FY 1977, about 280 structures have been completed. The total number expected to qualify for remedial action is about 600.

In addition, ERDA in a cooperative effort with EPA and the 8 states involved, is conducting engineering analyses of 22 inactive mill tailings sites to determine practicable remedial alternatives and costs. The site reports are expected to be completed in the next few months. Upon completion of the reports, ERDA plans to seek legislative authority and funding for a remedial program similar, in many respects, to that at Grand Junction.

Question. Have the potential health problems of persons living in homes built on sites using mill tailings been alleviated?

Answer. The remedial action program in Grand Junction, Colorado, which usually involves removal of the floor slab and excavation of the tailings, has been successful in lowering radiation levels in the structures. Priorities were established under which houses and schools were ranked highest. Radiation level in the structures was also used as a criterion. The Grand Junction program is about half completed.

Question. Is research currently underway to determine the possible health effects associated with the dispersion and use of these mill tailings?

Answer. The reports on the engineering analyses of the 22 inactive mill sites contain the results of studies of the elevated radiation levels in the vicinity of the tailings piles, and calculations of possible health effects. In general, the findings are that the risk of lung cancer is about doubled for those residing within ½ mile of a tailings pile for 30 years or more.

Question. How aware are the people who live in proximity of these tailings of the potential hazards?

Answer. In Grand Junction, Colorado, where the problem is most acute, and continuing publicity is given to the remedial program, the public is reasonable well informed. However, in other locations, the health authorities and civic leaders are generally aware of the problems, but the general public is not. This is reflected in the difficulties encountered in the past in preventing the misuse of these sites.

Question. How urgent is this situation in terms of health effects?

Answer. The history of lung cancer among uranium miners indicates that there is usually a long latent period between initial exposure and detection of cancer, on the order of 5 to 15 years. For the lesser radiation levels associated with the tailings piles the latent period may be longer, possibly 30 years or more. However, many of the existing tailings piles result from operations that began in the late 1940's and 1950's. Therefore, while the situation cannot be described as one requiring emergency measures, prudence dictates that remedial work be undertaken without undue delay.

Question. You stated during the hearing that a clean-up program for uranium mill tailings in the western United States would cost $80–$125 million. You also stated that you are discussing the situation with NRC to insure that the problem of mill tailing piles will not be neglected in the future. The Committee is left with the impression that the implementation of such a program would require separate authorizing legislation. It is not clear, however, whether NRC currently, has the jurisdiction to regulate this sort of disposal, or whether its statutory mandate ought to be amended to authorize it to assert control over naturally occurring radioactive materials. Please clarify this point.

Answer. The Committee is correct in its impression that implementation of a remedial program would require separate authorizing legislation.

NRC exercises its jurisdiction over the uranium milling industry through the licensing requirements of the Atomic Energy Act pertaining to possession of source material. Source material is defined by regulation as any material containing 0.05 percent uranium and thorium combined. Once the ore has been processed for recovery of the uranium it originally contained, the resultant principal waste product, called tailings. normally does not contain sufficient uranium or thorium to meet the definition for source material, even though most of the radioactive constituents of the ore remain in the tailings. Before enactment of NEPA, the AEC regulatory position was that it had no further jurisdiction over tailings once the milling process was completed. Currently, pursuant to NEPA, the NRC is requiring prospective licensees to make commitments fo rstabilization of tailings after operations cease. Once satisfied that the stabilization job is complete, NRC may terminate the license, whereupon its jurisdiction would cease. We would feel much more confident of NRC's ability to exert control over tailings sites if their licensing authority extended to all solid wastes created by processing natural materials for uranium and thorium. Due to the long-lived radioisotopes they contain the tailings piles become, in effect, long-term burial sites for low level radioactive wastes.

Question. During the hearings, Dr. Liverman referred to 8 or 10 sites left over from the Manhattan Project which could present cleanup problems. When will the survey of these sites be completed?

Answer. It is anticipated that all necessary radiological surveys of the excessed sites will be completed on or before September 30, 1978. To date, 29 surveys have been completed and the final reports on those sites should be completed by the end of 1977. The remaining 15 sites yet to be visited and surveyed, as necessary, will be completed by the end of September 1978.

Question. Has there been any investigation as to why the documentation of these problem areas disappeared?

Answer. This question relates to the file searches for radiological documentation reports on formerly utilized (excessed) Manhattan Engineer District and Atomic Energy Commission sites. The lack of adequate radiological documentation on many of these sites resulted in part from the lack of recognition in records management programs of the importance of retaining such records in active or accessible files.

The ERDA file search indicated that records could not be located on the radiological conditions at some of the excessed sites. It has been determined that at some of these sites no documentation reports were ever prepared. In other situations, the radiological records had been destroyed through the normal records management retirement procedures for correspondence over 7 years old. A complication of this situation occurred in about 1950 when contract administration of many of these sites was transferred from the New York Operations Office in the early 1950's to the AEC Division of Raw Materials, Headquarters. This AEC division was abolished in about 1972 and most of the remaining contract administration was absorbed into the AEC Division of Production. These changes in management contributed to the dispersion of some of the early contract records to the Chicago Operations Office, the Oak Ridge Operations Office, and some to Federal records retirement centers. No efforts have been undertaken to identify files sent to the Federal records centers for storage.

Question. Where are these contaminated sites located? Are they within or near any population centers?

Answer. These two questions are answered briefly in the following list. Two sites are located in populated areas where offsite private properties are also affected. The rest of the sites are generally located in light or heavy industrial areas, and the radioactive contamination is generally limited to the plant site.

Middlesex Sampling Plant, Middlesex, N.J.—The plant site and some surrounding private properties are contaminated with radium-226. This plant is located in a populated area.

Ashland Oil Co., Tonawanda, N.Y.—This plant site is located in an industrial area and the contamination is essentially limited to the plant site.

Seaway Industrial Park, Tonawanda, N.Y.—This sanitary landfill site is adjacent to the Ashland Oil Co. site. Contamination is limited essentially to the landfill site.

Linde Refinery Site, Tonawanda, N.Y.—This plant site and some buildings are contaminated with low levels of uranium. The plant is located in an industrial area surrounded by light industry and some residences.

Canon Industrial Park, Canonsburg, Pa.—Extensive soil and building contamination exists at this industrial park. The industrial park is surrounded by a populated area.

E. I. duPont, Deepwater, N.J.—The buildings on this site are slightly contaiminated with uranium. The site is located in a heavy industrial area.

Mallinckrock Chemical Co., St. Louis, Mo.—Low levels of uranium contamination have been identified on some building surfaces. This plant is located in an industrial area.

St. Louis Airport Storage Site, Lambert Field, St. Louis, Mo.—This undeveloped land site has soil contaminated with uranium and radium. It is located in an industrial area.

Blairsville Site, Pennsylvania.—This railroad property contains low level radioactive waste material moved from the Canonsburg site for landfill purposes. It is located in a rural area of low population density.

Site A, Palos Park, Illinois.—This site contains a burial ground used by the University of Chicago during Manhattan Project operations in the 1940's. It is located in an underdeveloped area of the Cook County Forest Preserve.

University of Chicago, Chicago, Ill.—Two laboratory buildings on the University campus have low levels of surface radioactive contamination. These buildings are currently used by the University.

Harshaw Chemical Co., Cleveland, Ohio.—This very large building is located in a heavily industrialized area. Building surface and soil contamination were found to be above acceptable levels.

Simonds Saw and Steel, Lockport, N.Y.—This building was found to have localized sports where radioactivity was detectable. It is located in a heavy industrial area.

Horizons, Inc., Cleveland, Ohio.—Surface contamination exists in the building. It is located in an area mixed with light industry and residences.

Question. On page 9 of your prepared testimony before the Committee it is stated that "Extensive environmental monitoring is conducted at all of ERDA's major nuclear facilities. . ." What is the goal or purpose of ERDA's environmental monitoring system?

Answer. ERDA's nuclear facilities have conducted routine environmental surveillance programs for radioactivity since the earliest days of the atomic energy program. The primary purposes of these routine environmental surveillance programs were to determine whether (1) facility operations, waste treatment, and control systems were functioning as designed and planned from the standpoint of containment of radioactivity, and (2) the applicable environmental radiation and radioactivity standards and effluent control requirements were and are being met.

Question. Does such monitoring occur periodically or continuously?

Answer. The routine monitoring programs are part of a continuing program including the continuous collection of effluent data and periodic (daily, weekly, monthly, etc.) collection of environmental media samples (air, water, soil, vegetation, foodstuffs, and biota).

Question. In case of sudden, high levels of radioactivity, would you be alerted?

Answer. Yes. Routine effluent monitoring programs of airborne and liquid releases as well as inplant monitoring of facilities and operations do provide immediate indication of increases in levels of radiation. Procedures are established that prescribe reporting of levels of radioactivity.

Question. How is such information made available to the public?

Answer. On an annual basis, each contractor is required to prepare an Environmental Monitoring Report which summarizes:

(a) The results of effluent and environmental monitoring for radioactivity and radiation levels, and estimates of potential exposure to the public, and

(b) the degree of compliance with applicable Federal, State, and local regulations and standards for pollutants both radioactive and nonradioactive. The reports are submitted to the public and Federal, State, and local agencies. Additionally, these individual site reports are also published in an annual ERDA compilation.

More frequently, reporting of environmental and effluent data is performed by several contractors depending on public or local interest. For example, monthly meetings are held with public health and county personnel and the Rocky Flats personnel at which time data and information are exchanged and discussed.

Question. Do you maintain an up-to-date recordkeeping facility?

Answer. Yes. Recordkeeping is in the form of annual environmental reports, the raw data for which are retained at each facility. For effluents, ERDA maintains two computerized information systems which receive annually information on quantities of radioactivity released by each site. These systems maintain a historical record of release data.

Question. Please describe the effluents which you monitor.

Answer. Effluent monitoring for radioactivity includes all principal nuclides released in each airborne and liquid effluent and onsite discharge stream. For nonradioactive pollutants those specific substances identified in air quality regulations or in NPDES permits for liquids are monitored.

Question. How much money is spent on monitoring per year?

Answer. It is difficult to estimate the dollars spent on effluent and environmental monitoring but the most recent estimate, submitted to OMB in October 1976, is in excess of $20 million.

Question. You refer to studies that are being conducted in "a variety of places where significant levels of radionuclides have been released, such as Rocky Flats . . ." What are the results of these studies?

Answer. The environmental studies referred to deal with research into the mechanisms of movement of the transuranium elements in the environment and how they may change in various physiographic provinces where nuclear facilities are located. Our results to date indicate that greater than 99.9 percent of the plutonium released to the environment remains in soils and sediments. Of the small fraction found in biota, a major portion, about 90–99 percent is transferred from soil by physical processes of resuspension onto plant surfaces and animal pelts. An extremely small percentage is transferred to plants by root uptake in the food pathways to man and appears not to be a health hazard at the environmental levels found beyond ERDA facilities.

Question. In general, do you provide your data to EPA on more than a yearly basis?

Answer. These kinds of data are not routinely transmitted to EPA but are produced in topical reports and for scientific journals. The objective is to accumulate sufficient information so that predictive models for the environmental behavior of the transuranium elements can be made.

There is a routine monitoring program which measures the concentrations of radionuclides in the environs of certain ERDA facilities which coordinates with EPA:

At the Nevada Test Site there have been studies of the extent and nature of the radionuclide distributions. For those same locations, additional studies have concerned possible transport of the contamination to air, water, vegetation, small animals, and cattle. There is an interchange of this information with EPA through annual colloquia of the Nevada Applied Ecology Group.

At Rocky Flats Plant Site, where there is a small amount of distributed contamination, there have been studies of transport to vegetation, animals, and cattle; also, there has been a concentrated study there of an aquatic environment. Air and water have been monitored continuously for many years. All of the monitoring information is discussed each month with the Rocky Flats Monitoring Committee of which EPA is a member.

At Mound Laboratory there have been studies of plutonium-238 contamination that has been carried offsite in a drainage ditch. Air and water monitoring are done and reported to EPA annually.

At LASL there is a small amount of offsite contamination. Air monitoring is done; also, vegetation and animal life have been studied for possible uptake of contaminants. LASL monitoring data are published annually and are provided to EPA.

Question. Does your monitoring system interact with EPA's to a significant extent?

Answer. The ERDA environmental monitoring programs are site specific, i.e., they are designed with a facility and a specific set of problems in mind and they are geographically limited to locales around the site. In this respect, they do not interact with EPA systems which are generally designed to broadly sample across the United States. However, in special cases such as fallout sampling, the ERDA programs supply data to assure a complete coverage of potential fallout patterns. The environmental program at the Nevada Test Site is designed to cover the Western United States and in that respect duplicates part of the EPA network.

Question. Is ERDA promoting standardization of facilities as means of improving the safety of nuclear power plants?

Answer. An authorization request of $12.4 million B/A for FY 1978 ERDA funding of Light Water Reactor (LWR) Plant Standardization is included in the Senate Energy and Natural Resource Committee Bill and is pending authorization action by the House Science and Technology Committee. EDRA supports this request to develop and demonstrate plant standardization owing to the contribution standardization will make to the National Energy Plan (NEP) goals of reducing the licensing and construction delays of LWR's planned or to be committed in the future. The completion of plant standardization efforts already initiated is necessary in order to achieve "one-stop" licensing and to facilitate the prelicensing and utilization of banked sites for future power plant construction. This could reduce the licensing by as much as 2 years and reduce direct construction costs and schedules by $50 million and 1 year respectively. These objectives are not adequately being addressed by private sector initiatives because the industry's ability to make further investments necessary to complete customized plant designs for "one-stop" licensing review is currently seriously impaired. Therefore, the detailed and final designs needed for initial "one-stop" license application can only be achieved by standardized reference plants.

Although plant standardization will improve the safety of nuclear power plants through more reliable operation the principal motivation for this proposed program, consistent with the NEP, is to enhance the utilization of LWR's to offset a share of the Nation's energy deficit without undue risk of proliferation.

Question. On transportation of nuclear materials, what does ERDA do if its recommendations are not acted upon by NRC and DOT?

ERDA's actions in this event would depend upon the degree of detrimental impact, if any, on its operations. The final regulatory decision is up to NRC and DOT. ERDA could appeal if the action were adverse to ERDA's interests. Part of our effort in ongoing risk assessments and analyses, and confirmatory testing of modeling and analytical design techniques, is to assist NRC and DOT in their rulemaking efforts. Continuing close coordination between the staffs of ERDA, NRC, and DOT affords the opportunity to discuss ERDA's recommendations and determine the appropriate action to take.

Question. Has this ever happened?

Answer. No.

Question. What additional procedures, if any, are needed to ensure that nuclear materials are transported safely?

Answer. Protection of the public health and safety is a prime consideration for ERDA as well as DOT and NRC. The present packaging requirements which are published in the DOT and NRC regulations, and shippers' compliance therewith, has resulted in an outstanding safety record. In more than a quarter century of shipping radioactive materials there has not been a single incident which resulted in death or injury due to the radioactive nature of the material. Comprehensive risk assessment studies show that the risks to the public from nuclear shipments are comparable to the risks of being killed by a meteorite. Many environmental impact studies have gone through the formal review process; they all point out that the risks are very small. ERDA's testing and analysis programs have verified that the risks are already very low indeed. They are probably not worth trying to make even lower, based on the various cost-benefit studies which have been done. Nuclear shipments are made safely now, and we expect this experience to continue.

Question. What is ERDA's position on the Rasmussen report (AEC/Nuclear Regulatory Commission's Reactor Safety Study, An Assessment of Accident Risks in Commerial Nuclear Power Plants, WASH-1400)?

Answer. ERDA's position is that the study met its stated objectives of making an "estimate" of the public risks that could be involved in potential accidents in commercial nuclear power plants (LWR) and to compare these "estimates" with other natural and man caused nonnuclear accident events.

Its weakness is that the public and others are undecided how it should be used. This problem is being addressed this year by the Nuclear Regulatory Commission Risk Assessment Review Group. This Federal advisory committee was established to review the Rasmussen Report and make recommendations to NRC on both the risk methodology and how it could be factored into the regulatory process.

In addition, the results of the study must be used in the context of the stated objective. They cannot be taken out of the context of an "estimate," that is, an attempt to make absolute comparisons of nuclear and nonnuclear accident events assuming that the maturity of the data used is equal. Most of the nonnuclear data presented is based on a number of statistically significant actual accident events. On the other hand, there have never been any commercial nuclear power plant accidents resulting in nuclear-related fatalities, nor has there been enough actual reactor years of operation to provide the same degree of maturity to the nuclear data as to the nonnuclear data. Since the estimated probability of a significant nuclear power plant accident is very remote, it will take many decades of operation of hundreds of reactors to increase the maturity of the nuclear data to a point approaching that of the nonnuclear data.

In summary, studies of this type are useful in estimating the risks of any new technology in order to enable the public to better weigh potential risks against potential benefits in determining whether, and how, to pursue its development. They can also provide information on what subsystems and components affect safety to the greatest degree, and which, therefore, need emphasis during plant design and development program.

ERDA is using the results of an HTGR risk assessment study which uses similar methodology to WASH-1400 as a guide in identifying key areas of HTGR safety research which are needed. ERDA has used, and DOE will continue to use, every reasonable method at its disposal to insure that safety is recognized as an integrated part of the design criteria and development program for nuclear systems.

Question. In 19ı2 the BEIR report gave its stamp of approval to the linear hypothesis; since then, new doubts have been raised. Articles by Dr. Irwin Bross, Drs. Mancuso and Stewart and Dr. Ernest Sternglass seem to indicate that the problem of effects at low levels of exposure are more serious than the linear hypothesis would predict. Is there a need to reexamine the linear hypothesis?

Answer. The stamp of approval the BEIR report gave to the linear hypothesis was adopted as a conservative method of estimating health effects from low dose radiation exposure. For low LET (Linear Energy Transfer) radiation such as X-rays, gamma rays or beta particles found in fission products or fallout there is a large body of data derived from studies at the Inhalation Toxicology Research Institute (ITRI), the Oak Ridge National Laboratory (ORNL), the Argonne National Laboratory (ANL), and the Los Alamos Scientific Laboratory (LASL) indicating that effectiveness of radiation dose in producing biological damage decreases as the dose is spread out in time. This ability to repair radiation damage produced at low dose rates is being considered by the BEIR committee in their reevaluation of the linear hypothesis for low LET radiation. The hazard from low dose rate exposure is less than predicted using the linear model and standards may be revised to reflect this ability to recover from radiation damage. Studies at the Brookhaven National Laboratory (BNL), ORNL, ANL, the University of Utah, and the Pacific Northwest Laboratory (PNL) using high LET radiation such as neutrons and alpha particles show much less repair of biological damage. Laboratory studies (Utah, ANL, PNL) suggest that hazards of high LET radiation to do not decrease as the dose rates decrease. The shape of the dose response curve needs to be further defined at low total doses for this type of exposure.

The studies cited in Question 13 suggest a unique response to low dose low LET radiation exposure. The Mancuso-Stewart studies are described in more detail in Question 14.

Dr. Sternglass has published a large number of articles where he interprets his epidemiological data as supporting the concept that there is a uniquely damaging effect of radiation. These health effects are postulated to occur at doses in the range of the natural background (40–200 millirem per year). However, studies (ANL, NCI) show a negative correlation between natural radiation levels and cancer incidence, which suggest that radiation at this low level cannot be assigned a determinant role.

The molecular and cellular mechanism used by Dr. Sternglass to explain the low-dose-rate biological effects is that per unit dose the damage to the cell membrane increases as the radiation dose rate decreases. This was derived from an artificial cell membrane system which was degenerating and addition of free radicals catalyzed the auto-oxidation and breakage of the membrane. Very extensive experimental radiation research using molecular, cellular, and lifetime observation of several animal species show no evidence to support this hypothesis. A cause-effect relationship between cell membrane alterations at low doses and pathological changes in the intact animal has not been established.

Many statements and scientific reviews were made by members of the international scientific community in response to the claims by Dr. Sternglass on the hazards of low level radiation from fallout. These were compiled by the Atomic Industrial Forum and summarized by the U.S. Atomic Energy Commission, Division of Biology and Medicine. The hazards of low level radiation are under continuous review by the National Academy of Sciences, the National Council on Radiation Protection and Measurements, and the International Commission on Radiological Protection. The conclusions of all these groups represent the consensus of the scientific community and disprove Dr. Sternglass' claims—that fallout has produced significant health effects.

Dr. Bross' hypothesis is that certain human subpopulations are very sensitive to exposure to environmental insults. These subpopulations are postulated by Dr. Bross to develop cancer following low doses of radiation. If they are very sensitive to radiation, the shape of the dose response curve would be changed by this subpopulation so that a linear extrapolation from high dose data would underestimate the response at low doses. Experimentation is underway to identify and define the radiation response of subpopulations, i.e., animals with unique genetic background (BNL, ORNL) or aged (Utah, ITRI) and sick animals (ITRI), that will help determine if they are very sensitive to radiation-induced changes.

There is a continuing need to reexamine the shape of the dose response curves and the models used to predict the potential health hazards from ionizing radiation. Many research projects (ORNL, ANL, ITRI, PNL) are designed to determine the shape of the dose response curves under a variety of exposure conditions. Other research (ANL, UCD, LASL, BNL, ORNL) is directed to understanding the biological mechanisms at the cellular and molecular levels which produce the changes observed in the animal experiments. This combined research approach provides a valuable data base used by committees like BEIR, NCRP, and ICRP in risk evaluation. Such committees use these data to develop standards made to ensure that the health and welfare of the public will be protected.

Question. Have funds been spent in fiscal year 1977 for this purpose? Are funds budgeted in fiscal year 1978?

Answer. In this broad context, funds for investigation and evaluation of the linear dose-response hypothesis were allocated in fiscal year 1977 and are budgeted for fiscal year 1978.

Question. Dr. Mancuso's study of Hanford atomic workers was being funded by ERDA, but after an unfavorable peer review, his funding was terminated. Was his research reviewed by radiologists or epidemiologists?

Answer. The contract with the University of Pittsburgh, "Study of the Lifetime Health and Mortality Experience of ERDA Contractors," principal investigator Dr. T. F. Mancuso, was routinely reviewed over the years. The expertise of the members of the review teams primarily reflected the areas of biostatistics and epidemiology.

Question. Why was his support discontinued?

Answer. The decision to terminate the contract with the University of Pittsburgh and to transfer the study to Oak Ridge Associated Universities (ORAU) was made because of deficiencies in performance under the contract. These included a reluctance to initiate analyses of available data, to publish papers in edited journals, and to have the contents of their reports quoted or cited. Also, serious questions were raised at the scientific reviews about the quality of the statistical analyses. Major disagreement between the investigators in the study and ERDA scientific staff arose from the investigators' desire to enlarge the population under study to include all major AEC/ERDA facilities. ERDA staff was of the opinion that enlarging the study would not solve the intrinsic deficiencies of the study and that the biases that tend to make control populations imperfect are independent of the population size in a study of this type. Accordingly, the study was transferred to ORAU so that completion of data base and analyses can proceed on a more timely basis.

With regard to the reference to studies by Drs. Mancuso and Stewart in Question No. 13, results of the analysis of the cause of death of Hanford workers by Drs. Mancuso, Stewart, and Kneale have now been published in a final report to ERDA. A review of this report by an *ad hoc* committee, consisting of experts in radiation epidemiology and other independent experts, indicates that the claimed increased incidence of cancer in Hanford workers appears to be the result of inappropriate use of statistical methodology. Hence, the results of the Mortality Study of the Hanford workers cannot be used to evalute the validity of the linear hypothesis.

Question. EPA has revised the uranium fuel cycle exposure standard to 20 mrems/year. Does ERDA comply with this standard?

Answer. The EPA regulations by definition apply to "radiation doses received . . . as the result of operations which are part of a nuclear fuel cycle." Thus, the regulations do not apply to ERDA facilities except those parts of the gaseous diffusion plants providing enrichment services to the electric utilities, and these do comply with the EPA standard.

Question. If the new evidence on the nonlinear hypothesis is considered valid, would ERDA or NRC revise this standard further?

Answer. As this is an EPA regulation, it would be incumbent on them to revise the standard rather than NRC or ERDA. Should such information be developed through ongoing ERDA research, our assistance in revising standards, as necessary, could be counted on.

Question. In your prepared testimony, you refer to "the latency effects in humans . . .". What is the range of latency periods for various radiation effects in humans and do we have an understanding of the variation in these latency figures?

Answer. The mean latency for radiation-induced tumors in humans depends on a number of factors related to the type and magnitude of radiation exposure, the characteristics of the population exposed, the characteristic of the type of tumors induced and the circumstances of surveillance of the exposed populations. From published estimates, the mean latency of radiation-induced malignancies for different types of tumors ranges from 20 to 30 years. Moreover, by nature of the methods used to determine mean latency, the values quoted are unlikely to over-estimate the value and the true value for some malignancies must be much larger. In addition, new cases of radiation induced tumors may continue to appear at a much longer period following exposure.

Example of the complex interrelation between population characteristics and radiation exposure is demonstrated by findings on the incidence of leukemia, breast cancer and lung cancer in the Japanese populations in Hiroshima and Nagasaki.

Type of leukemia	Time of maximum risk of leukemia following exposure—age at time of exposure (years)			
	Less than 15	15 to 29	30 to 44	More than 45
Acute form	6–7	10	15–16	>20
Chronic form	6–7	7–8	9–11	-------------

It is evident that the younger at the time of exposure the greater risk at an earlier period while in the group aged 45 or more the greatest risk occurs later. With regard to the latter group, there is no evidence at present that the risk for leukemia has returned to the levels in the controls.

An increased incidence of breast cancer in women who were exposed was noted before 1955 in older women and is now being maintained and augmented by women who were younger when exposed. Based on information available now, it appears for those women who were below 10 years of age at time of exposure, the peak effect lies well in the future, i.e., a latency period of more than 30 years.

An analysis of the data in 1957–1958 suggested that the incidence of lung cancer was significantly elevated in exposed populations. Since then, three dose specific analyses have strengthened the evidence. Even more than is the case of breast cancer, the increased incidence now visible is in the older age groups at time of exposure. There is every reason to expect that the peak effect for those below the age of 35 years at time of exposure lies in the future.

Question. Are the epidemiological studies conducted at Los Alamos and Argonne contributing to this effort?

Answer. The epidemiological study of the radium dial painters at ANL indeed has contributed significantly to various factors that determine the latency of tumors induced by radium. The LASL epidemiological study of plutonium workers, initiated in 1974, will, in the near future, develop information on tumor latency in this population.

Question. What is their present status and what preliminary findings have been reported, if any?

Answer. *Status of Studies on Radium-Exposed Human Populations* (Argonne Radium Studies). Much of the research effort on radium effects has been aimed at clarifying dose-response relationships between radium exposure and bone cancer. The rationale for such work is its relevance to assessment of risks related to other almph-emitting radionuclides, to which human populations may be exposed (e.g., plutonium, thorium, uranium).

In addition to studies on bone cancer (including incidence rates, "latency" periods, dose-response functions), however, other possible health effects are being assessed through studies on mortality from various causes (site-specific cancers and other chronic diseases).

More detailed descriptions of the results of these studies are provided below.

BONE CANCER

A theory of the induction of bone cancer by alpha radiation is being developed, and an extensive preliminary report has been published (Marshall and Groer, 1977). Using data on humans exposed to radium, the evidence at present supports a dose-square model better than a linear (or linear + square) model; more definitive conclusions await a more thorough cohort analysis and more complete follow-up on human populations. The theory (Marshall and Groer, 1977) provides some predictions on the bone tumor rate over time and the relative effects of alpha-emitting nuclides with different half-lives, and describes the possible mechanisms and stages of carinogenesis involved.

An analysis of "latency" periods or appearance times of bone cancer in radium-exposed humans (a subgroup composed of early female dial painters) has recently been completed (Polednak, in press). The time period from first exposure to diagnosis of bone cancer ranged from about 5 to 52 years, with a log-normal distribution. Although mean and median latency periods declined with increasing intake levels of radium (measured in microcuries), this apparent effect of intake dose was due to "competing risks" (i.e., a dose-related increase in mortality from causes of death other than bone cancer). Correcting for this effect by life-table methods, incidence rates from bone cancer were consistently higher in a higher intake-dose group (than in a lower intake-dose group) at each time period after exposure. There was no significant effect on intake-dose, at tumor-producing levels, on the pattern of incidence rate over time after first exposure to radium.

Other current analyses have involved dose-response relationships for bone cancer in the best-defined and most-completely followed-up radium cases—i.e., the early female dial painters (first employed before 1930). Again, present data provide more support, in a statistical sense, to a dose-squared relationship (Rowland, Stehney and Lucas). Current efforts are concentrated on measurement of radium body-burdens in this group, either by exhumation (for the deceased) or increased efforts for cooperation in the study (for those still alive). Sample sizes are of critical importance in evaluating dose-response relationships. The implications of this research concern risk assessment of human exposure to alpha-emitting radionuclides, recognizing that there will be differences among these radionuclides in terms of probable route of exposure, metabolism, organs at risk, and expected effects.

MORTALITY STUDIES

A recent report (Polednak, Stehney and Rowland, in press) presents data on mortality from various causes in a group of women first employed before 1930 in the dial-painting industry, and who were ascertained from sources largely unrelated to outcome (i.e., mortality). This is the most "unbiased" group of radium-exposed humans, since inclusion in the study was not dependent on presence of symptoms or disease, or level of exposure. Some 640 (or 88.3%) of these 725 women have been followed up in terms of mortality.

Based on health rates for U.S. white females, greater than expected numbers of death (from death certificates) were observed for all causes (240 observed vs. 196.7 expected), "bone cancer" (22 vs. 0.3), cancer of other and unspecified sites (18 vs. 2.6), diseases of blood and blood-forming organs (4 vs. 1.1) and "external" causes (31 vs. 10.2). Six of 22 certificates coded to "radiation accident" (an "external" cause) also mentioned bone cancer. From sources other than death certificates, many of the "other and unspecified" cancers were shown to be cancers of bone and/or sinuses (mastoid or paranasal). No other causes of death showed statistically significant increases over expectation.

Dose-effect relationships were assessed indirectly and directly. Compared with women first employed in 1915–24, those first employed in 1925–29 had low cause-specific mortality ratios (observed vs. expected numbers of deaths) and an overall mortality ratio of 0.80 (or 80% of expected). This pattern corresponds remarkably to well-documented changes in work habits in the industry; i.e., in 1925–26, oral contact with paint brushes was prohibited, leading to reduced intake of radium.

In comparisons by time period (<1945, 1945–64, and 1965–75), a significant excess of deaths from leukemia and diseases of blood were observed before 1945 only.

Due to problems of bias in follow-up, only the late effects of radium exposure could be assessed directly in terms of dose (intake level). Among women alive in 1954 (when extensive studies were initiated) and measured for radium body-burden at least once while living (in 1954 or later), observed mortality was compared with that expected on the basis of U.S. white female death rates. Follow-up was from the year of first measurement of radium body-burden. Total mortality (from all causes of death) was analyzed in 5 intake-dose groups. For 3 groups below 50 μCi, total deaths were less than expected (i.e., about 80 percent of expected), while for two higher dose groups (>50μCi), total deaths were greater than expected (i.e., about 200 percent of expected). Cause-specific mortality was analyzed in two dose groups (<50 and $\geq$50 μCi). In the lower dose group, the only cause category with a significantly greater number of observed than expected deaths was cancer of the colon; the mortality ratio for all causes was 0.82 (or 82 percent of the expected number of deaths). In the higher dose group, the mortality ratio for all causes was 1.88 (or almost twice the expected number of deaths). The possibility of a causal association between lower-dose radium exposure and cancer of the colon needs to be explored further, by continued follow-up of the present group of measured women, and clinical studies (to verify diagnoses and describe the pathology). The present findings are not proof of causality, since a large number of comparisons were made, and some may reach the conventional level of statistical significance merely by chance alone.

No bone cancers or leukemias were observed in measured persons with an intake of <50 μCi of radium.

In this study of late effects of low level of radium, a cut-off point of 50 μCi was used. For a woman who worked for one year (about the average for this group) and had an intake of 50 μCi, the maximum body burden of radium-226 was about 2.5 μCi. This is about 25 times the radiation protection guide of 0.1 μCi of radium-226, regarded as being the maximum permissible body burden from occupational exposure, and as being relevant to other bone-seeking radionuclides such as plutonium-239 in humans.

Further work should concentrate on the following areas: (1) use of morbidity data, in view of the limitations of death certificates; (2) obtaining body-burden measurements on these early dial workers who are now unmeasured. The second point is relevant to the accuracy of the above conclusions regarding dose-response relationships, as well as those specifically dealing with bone cancer and models of induction described above. In the above-mentioned mortality study (Polednak et al.. in press), about 70 percent of those women still alive in 1954 had had a body-burden measurement. Although such response rates are not unusual in epidemiologic studies, questions exist about the generalization of findings on the measured group to the total group.

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Question. According to your testimony, studies of the health effects of radiation are being conducted by several groups. You caution, however, that these are lifetime studies of latent effects of radiation and, therefore, short-term information is preliminary. However, some of this information dates back a generation, such as the plutonium workers of 1942, the thorium workers from 1935 to 1974, and the radium dial painters.

How is this data being used by your Division of Operational and Environmental Safety to ensure the safety of workers currently exposed?

Answer. The radiation workers exposure standards which are adopted by ERDA are based upon the recommendation of the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection. These organizations have access to the results of the epidemiological studies and use them as a basis for standards development. In addition, the Division of Operational-Environmental Safety monitors the current studies to see whether there is evidence which questions the adequacy of our standards.

Question. In the study conducted from 1944 to 1945, 26 workers at Los Alamos were examined for effects of plutonium deposition. You state that "no evidence of disease associated with plutonium deposition was observed". What were the levels of exposure?

Answer. Of the 26 workers, 2 workers have more than 5 maximum permissible body burdens (MPBB), 18 have between 1 and 5 MPBB and 7 have less than 1 MPBB.

Question. You say that research emphasis is given to exposures to low levels of external radiation that might occur in work areas or in the general environment. Can you describe this research in more detail?

Answer. ERDA supports animal research using both dogs and rodents to determine the hazards associated with low levels of external radiation. These projects are designed to aid in evaluation of the long-term health consequences of both high LET (neutrons) and low LET (gamma rays) radiation. Since cancer induction is a principal hazard of low level radiation exposure and since the time between exposure and cancer appearance may be very long, it is essential to obtain data from long-lived dogs as well as rodents.

At Argonne National Laboratory (ANL), special facilities are available for continuous exposure of dogs to low dose rates (35–0.4 rads/day) gamma irradiation. Dogs were exposed at dose rates of 35, 17, 10, and 5 rads/day to reach total doses of 600–4000 rads. Lifetime observations have been completed on these dogs. At 5-10 rads/day, 50 percent of the dogs developed myelogenous leukemia. Doses of 10 r/day interfere with normal development of the testes and 5 r/day causes changes in developing ovaries. These exposures are, of course, much higher than the maximum permissible occupational dose of 5 rems per year. Additional experiments have been initiated in which dogs will be exposed to lower dose levels (5, 2.5, 1, and 0.4 rads/day) throughout their lifetime. This research will make it possible to evaluate the effects of lifetime exposure to lower doses and dose rates.

Studies at the University of California, Davis (UCD) complement those at ANL by evaluating the cellular changes induced in bone marrow under exposure conditions that lead to the induction of leukemia. These studies which utilize dose rates of 15, 5, 1.5, and 0.5 rads/day are designed to gain information about the mechanism of transforming normal cells to leukemia and also to attempt to develop sensitive cellular indicator systems of low-level radiation damage.

Groups of pregnant female dogs (ANL) are exposed to evaluate the effects of *in utero* radiation. The offspring are studied to determine tumor induction and developmental patterns. The sensitivity of *in utero* radiation exposure can thus be evaluated and used to estimate hazards. The study will also determine if reproductive integrity is maintained following *in utero* and lifetime low dose rate exposures. This is important in light of the observations made at Lawrence Livermore Laboratory (LLL) that the developing ovary is very sensitive to radiation damage.

Rodent studies are useful in establishing the relative risk of exposure to low dose and dose rate radiation of different types. At ANL and Oak Ridge National Laboratory (ORNL), rodent studies have been completed to determine the shape of the dose-response curves for neutrons and gamma rays using either chronic or fractionated radiation schedules. The results in terms of life shortening and cancer induction following neutron exposure have been compared with data derived from animals receiving gamma ray exposure. Thus, it is possible to determine the relative hazards of the two exposure types at high and intermediate doses. For neutron exposures at intermediate doses, protraction of the dose over a longer time period or fractionation of the exposure into several small doses increases the amount of life shortening and cancer incidence per unit of dose above that measured following a single exposure. In most experimental systems, the neutron exposures seem to be more damaging than gamma exposures. Studies are in progress which extend these observations to much lower dose rates and total doses. These rodent studies utilize dose rates of 0.2, 0.8, 3.2, and 12.8 rads/day to produce total doses of 2.5, 5, 10, 20, and 40 rads. With these 20 group of mice, it will be possible to determine the effects of both low dose and dose rates on the shape of the dose response curves for the induction of radiation-induced disease by neutrons. The hypothesis that low dose rates produce a higher frequency of cancer than predicted by high dose rate studies can, thus, be tested. This information will be useful not only for evaluating the hazards from neutron exposure but will form a part of the data base for risk evaluation for alpha emitters and other high LET radiation.

Animal studies (ORNL) on the genetic hazards from low levels of external radiation form the data base for evaluation of this hazard in man.

In female mice, high dose rates produce significant mutation rates while low dose rates exposures do not increase the mutation rate above that observed in controls. Studies at low dose rates indicate that somatic cell chromosome aberrations (ITRI, ORNL) and gene mutations in male mice (ORNL) decrease as the dose rate is lowered to levels of about 1.0 r/min. Further reduction to very low dose rates .005 to .0007 r/minute gives no further reduction in mutation or chromosome aberration frequency. Other studies are in progress to evaluate the physiological and genetic significance of mutations and aberrations since all these may not produce adverse effects in offspring.

The data thus suggest a decrease in genetic hazard with a decrease in dose rate for low LET radiation.

The following research projects are concerned with the biomedical effects of radiation on human populations.

1. A study of the health and mortality of workers in the nuclear industry in Hanford and Oak Ridge since 1942 (approximately 130,000).
2. A study of the health and mortality of all U.S. plutonium workers since initiation of the Manhattan Project (approximately 15,000).
3. A study of the health and mortality of A-bomb survivors in Japan (approximately 109,000).
4. Medical surveillance of Marshallese exposed to fallout from nuclear weapons tests (approximately 150).
5. A study of the mortality of persons with internal deposition of radium (3100) and thorium (4500).

With the exception of a relatively small group of A-bomb survivors in Japan, these populations have been exposed to low levels of external or internal radiation.

Question. Does the Transuranium Registery form a large part of your data base?

Answer. The U.S. Transuranium Registery (USTR) is developing a data base of workers with known depositions of transuranic elements. As such, the information collected on long-term biological effects as a function of actual tissue deposition is a vital part of the epidemiological study of plutonium workers.

Question. How can this be considered a reliable source of information if participation by various facilities is strictly voluntary?

Answer. There exists excellent cooperation on a voluntary basis of the laboratories and contractors with the USTR in this effort which makes this a highly reliable source for valuable information.

Question. You have testified that ERDA is giving special research attention to the dangers of inhalation exposure of radioactive materials because of its significant exposure potential. How often do accidental releases of radioactive materials into the atmosphere occur?

Answer. In the last several years, accidental releases of radioactive materials have occurred rarely. The following is a listing of reportable incidents which resulted in an atmospheric release.

Year	Radionuclide	Location
1970	Tritium	Lawrence Livermore Laboratory.
1974	Tritium	Savannah River Laboratory.
1975	UF_6	Portsmouth.
1975	UF_6	Portsmouth.
1975	Tritium	Savannah River Plant.
1976	85_{kr}	Oak Ridge National Laboratory.

In the last 6 years these six incidents were those reportable under criteria established by ERDA for reporting and formal investigation of accidental releases.

Question. What materials are released and in what phase of the nuclear energy cycle?

As indicated above, the nuclides released were tritium, ^{85}Kr, and UF_6. The UF^6 is used in the enrichment process and as such is the only release related to the nuclear fuel cycle. The remaining releases were from research facilities or from facilities involved in ERDA's weapons development programs.

Question. Is the inhalation exposure resulting from these releases the only source of serious exposure hazard?

Answer. These releases have not resulted in a serious exposure hazard to either the occupational or offsite population at ERDA facilities. There are other pathways through which potential exposures could occur, for example, liquid effluents. However, no serious exposure hazard has been shown to be a consequence of these pathways.

Question. How serious a threat to human health are these releases, both to workers at the nuclear site and the general population?

Answer. As reported in the annual Environmental Reports and presented at technical meetings, effluents from ERDA facilities are less than 1 percent of established standards. In fact, for all ERDA facilities, the relative percent of facility population dose to background (natural) population dose is about .02 percent and has remained at this level for the last 4 years. These values include those accidental releases that have taken place.

In the six incidents which were reported in the last 7 years, four workers received measureable radiation doses, all of which were less than 5 percent of the maximum allowable limit.

Question. You mentioned the implementation of a new program wherein the weather patterns around the site are analyzed, allowing the prediction of the direction in which a radioactive cloud would move and facilitating an evacuation should the situation warrant such action. Why has ERDA failed to consider this measure an essential part of its safety program before now?

Answer. All ERDA nuclear sites have an atmospheric release prediction system as an integral component of their emergency response measure. Each site has meteorological equipment, manpower and predictive tools tailored specifically to the site to respond to potential or actual incidents or accidents involving an atmospheric release of hazardous material.

The Atmospheric Release Advisory Capability (ARAC) development was conceived by the Division of Biomedical and Environmental Research in 1972 in response to the anticipation at that time that several hundred nuclear power reactors would be operating in the United States at the end of the 20th century. It was thought that the development of a centralized advisory service, utilizing state-of-the-art regional predictive models, computers, communications, and display systems would greatly reduce the need to duplicate these services at each site while at the same time improving predictive methods generally in use at the time.

The development of the system is nearly complete and the concept appears to be valid. Before offering the concept to the nuclear power industry, however, the plan is to equip a large number of ERDA nuclear sites with the ARAC system to prove its utility and demonstrate its validity. The implementation phase of this very expensive system is scheduled to add about two or more ERDA sites per year until all requiring the service are equipped.

Question. When will NRC begin implementing this technique and will it be required of licensees?

Answer. The Nuclear Regulatory Commission has been following the development of ARAC since its inception, but we are unable to answer for them what their plans might be.

Question. You mention techniques for treating individuals exposed to internally deposited agents, presumably including inhalation. What kind of techniques are these? How effective are these?

Answer. At present, the only drug available for treating individuals exposed to internal contamination with actinides is the tri-sodium calcium salt of diethylenetriaminepentaacetic acid (DTPA). DPTA binds actinides and accelerates urinary excretion thus preventing deposition in tissue. The agent is quite effective in reducing the body deposits of soluble actinides. In a recent case of unusually severe internal contamination with a soluble actinide, well over 85 percent was excreted within a 30-day period following contamination. In comparison, the biological half life of this particular actinide in the absence of treatment, is about 73,000 days. However, for the deposition of highly insoluble oxides or depositions that have become firmly bound to tissues, neither DPTA nor any other agent have been proven useful in decreasing internal deposition in animal studies and in man.

Question. How seriously do you view the possible health effects associated with increasing ionizing radiation exposure of the general public due to increasing use of diagnostic medical and dental X-ray procedures?

Answer. Conventional risk assessment is based on linear extrapolation, i.e., the relationship between effects and dose remains the same irrespective of changes in dose, dose rate or population at risk. Linear extrapolation is the only means to assign risk to exposure from most diagnostic exposures since at these dose levels epidemiological studies are not feasible. By using the linear extrapolation, it is implied that any dose contribution is associated with increased risk. On this basis, exposures should be kept as low as possible.

Question. How does the average population exposure from the nuclear fuel cycle compare with the average population exposure from such diagnostic procedures? How is it likely to change in the future?

Answer. The current estimated population exposures from diagnostic procedures is about 50 mr per year. Estimated annual dose contribution from current reactor operations and nuclear fuel cycle are approximately 0.04 mr per year. For the projected nuclear installed capacity of 3600 GW by the year 2000, the whole-body collective dose would be less than 3 mr per year. In comparison, the annual dose (whoe body) from natural radiation in the U.S. is about 100 mr per year.

Question. In his testimony Dr. Liverman indicated that coal-fired generators burning western coal would release significant amounts of radioactivity into the atmosphere. A recent New York Times article noted that some scientists had predicted that several thousand deaths would result simply from the normal, non-radioactive emissions that pollute the air. How much money has ERDA allocated to investigate the effects of increasing airborne pollutants, both radioactive and non-radioactive from an increase in the number of coal burning power plants?

Answer. The health effects program in ERDA does not specifically address health problems associated with radioactive pollutants from coal burning facilities. A recent report "Potential Radioactive Pollutants Resulting from Expanded Energy Programs" (EPA CHESS Report No. 6), from Stanford Research Institute estimates that with accelerated coal combustion in the ERDA National Plan for Energy RD&D the total radiation does to man will increase in the year 2000 to about 1,500 man rems per year which is less than 0.01 of 1 percent of the natural background radiation level. The airborne radioactive pollutants from coal combustion facilities with stack cleanup will be from the fly-ash particulates found in waste ash piles and ponds. Most will be from radioactive gases such as radon emanating from transuranic elements in the trapped fly ash. Some studies using experimental animals under controlled laboratory conditions indicate that inhalation exposure to radon gas in the absence of dusts is not a significant health hazard. The estimates given in the aforementioned report are for a "worst case."

The health effects program does not specifically address those problems related to radioactivity involved in coal combustion because the same pollutants are also encountered in parts of the nuclear energy fuel cycle. Such evaluations are therefore provided as part of the fiscal year 1978 allocation of $35.5 million for nuclear energy-related research. That program includes the necessary research to provide health risk estimates from low-level exposure to external radiation and those radionuclides to which man might be exposed at all stages of the nuclear fuel cycle from mining to disposal of radioactive waste. At the same time, that program addresses potential health problems identified with radioactivity encounterable in other energy technologies including coal combustion.

The fiscal year 1978 budget includes about $15 million for assessment of health risk from all coal technologies and allocates $3.9 million specifically for evaluation of the health effects of non-radioactive atmospheric and other effluents of conventional coal-burning facilities as well as advanced coal combustion processes (fluidized-bed combustion) under development in the ERDA fossil energy program.

The aim of these programs is to produce the types of comparative health risk data required for choice among the several alternatives available for increasing electric power production namely; nuclear, conventional, and advanced coal combustion.

Question. What alternatives are available in case the radiation dangers from coal are too great?

Answer. As indicated in the response to the above question, the radiation hazard from coal combustion by the year 2000 is estimated to be about 1500 man rem or 0.01 of 1 percent of that resulting from natural background radiation. This can be compared with estimates of about 130,000 man rem total dose from accelerated nuclear power development including breeder reactors and required fuel reprocessing facilities. Most of this total dose is from fuel reprocessing and represents less than 1.0 percent of that received from natural background radiation. Although the radiation hazard associated with coal combustion may be significant, it is not likely to be the major contributor to decisionmaking among the various alternatives for future energy production. In our present state of knowledge, it is easier to estimate the hazard from radiation than for most chemical pollutants. The ERDA health effects program is geared to providing the information that is needed to compare the health risk associated with the various options available for energy production and conservation. It also can provide the data required to improve methods for control of nuclear and chemical pollutants.

Question. What research is ERDA conducting on the health effects of high-voltage transmission lines?

Answer. ERDA is currently sponsoring a multidisciplinary program of research to identify and characterize health effects that may be induced by electric and/or magnetic fields associated with high-voltage (HV) overhead transmission lines (both DC and 60 Hertz AC types). This is a coordinated program jointly funded and managed by ERDA's Division of Electrical Energy Systems (EES), Division of Biomedical and Environmental Research (BER), and Division of Environmental Control Technology (ECT).

Research dealing with electric fields includes both biological studies *per se* and work conducted to characterize physical-chemical perturbations to which biological systems may be exposed in the vicinity of HV transmission lines. In the biological investigations, electric-field intensities under study vary over several orders of magnitude and span the entire ambient range. Summarized below are studies that are ongoing or just getting under way:

A study of animal responses to 60 Hertz electric fields (field strengths up to about 130 kV/m) is in progress at the Pacific Northwest Laboratories (PNL). Both rats and mice are being tested to determine possible effects of long-term exposures on a number of biological parameters including growth, development, reproduction, metabolic activity, endocrine function, immunologic competence, bone growth and structure, serum chemistry and hematology, nerve and neuromuscular function, behavior, and pathology. Only very preliminary data have been collected to date. A companion study in miniature swine is sponsored by the Electric Power Research Institute (EPRI).

In a second study at PNL, possible mutagenic effects of DC and 60-Hertz AC fields are under investigation in two genetically well-characterized systems, Drosophila (the fruit fly) and microorganisms. Bacterial cells are being exposed in an aqueous conducting medium while Drosophila (pupal stage) are exposed in air. This is jointly managed by EPA and ERDA/BER and is supported by EPA pass-through funds. Data collection is just beginning.

Psychocoustic responses of humans to audible noise associated with HV transmission lines have been under investigation at the National Bureau of Standards (Sound Division) for nearly two years. The noise of concern may be generated by corona phenomena during wet or humid weather. Although this noise is of relatively low intensity, it may constitute an annoyance in nearly areas. Behavioral measurement techniques are being used to evaluate aversiveness to the audible noise. A pilot study involving a small number of subjects has been completed, and data from the first full-scale experiment are being analyzed.

At the University of Rochester, a multifaceted study of biological responses to HV transmission lines is getting under way. Responses to 60-Hertz electric fields of various intensities and to transient electric shocks are to be characterized. Thresholds for perception of and aversion to electric fields will be studied in the rat. Responses to transient electric shock (spark discharge) will be similarly investigated. Physiological studies with rats and mice will be conducted to identify any somatic effects that may be induced by chronic exposure to electric fields. Additional studies with simpler systems grown *in vitro* or in tissue culture are planned to define effects of electrical fields on cell division, growth, differentiation, chromosome morphology, and viability. One purpose of the Rochester study is to test biophysical models which predict that the response of living systems to electric fields is a threshold phenomenon.

Another recently initiated project involves a joint effort by investigators at the Sandia Laboratories in Albuquerque and the Los Alamos Scientific Laboratory (LASL). In the LASL effort, mammalian cells are exposed *in vitro* (conducting medium) to 60-Hertz electric fields to evaluate possible genetic changes or perturbations of cell replication, growth, or survival. Effects on chromosome structure will also be investigated. These experimental activities will be closely integrated with a theoretical study at Sandia of rate processes in both exposed and unperturbed systems. A study of bioeffects of 60-Hertz magnetic fields will be added during the next year.

The ERDA staff (in EES) has been participating in the management of a project at the University of California (Los Angeles) which has been jointly funded in the past by EPA/DHEW/ONR and in which possible effects of 60-Hertz electromagnetic fields on the central nervous system (CNS) are being evaluated. The study is planned so that effects on CNS function and behavior can be identified and correlated with measured changes in brain rhythms and neuronal membrane conditions. ERDA was recently added to the list of fiscal sponsors for the UCLA project.

The Sanford Research Institute is currently reviewing and analyzing recent literature dealing with health/environmental impacts of HV overhead transmission lines in order to assess the adequacy of environmental control technologies.

A study of electric field instrumentation and calibration is being conducted by the staff of the Electricity Division, National Bureau of Standards (NBS). The objectives of this project are to evaluate devices and methods in current use for measuring electric and magnetic fields associated with HV, AC and DC transmission lines, to assess methods being used for calibrating such devices, to develop and document a recommended standard procedure for performing calibrations, and to establish a calibration facility at NBS. Work on AC field meters is nearing completion.

A study recently initiated by the General Electric Company will establish a data base on the characteristics of electric fields and air ion concentrations that are associated with DC transmission lines operating from ±600 kV to ±1200 kV. The data base will be assembled from measurements made near and under a DC line. Data will be collected under diverse weather conditions and for a variety of conductor configurations and line voltage levels.

The Federal Register of March 18, 1975, carried a notice from EPA requesting information and data on health/environmental effects of transmission lines energized to 700 kV or higher. Over 50 responses from a variety of sources were received. A preliminary review of these responses as well as information from other sources failed to identify any acute impacts. A detailed analysis of the information submitted in the 50 responses is needed, however, and work on this task is now getting underway at the Illinois Institute of Technology Research Institute under joint funding by EPA and ERDA. The analysis should be completed in one year.

All ongoing studies of magnetic fields were initiated in Fiscal Year 1977 and, accordingly, are not far advanced. Although these are, at present, generic studies (not necessarily limited to any one type of magnetic field) primarily concerned with relatively high field strengths, they will nonetheless provide valuable baseline data relevant to bioeffects that may be induced by the weak fields associated with HV transmission lines. The following work is in progress:

At the Lawrence Berkeley Laboratory (LBL), a variety of experimental systems is being used to identify and characterize biomagnetic phenomena, particularly generic phenomena. A principal objective of the LBL project is to develop an understanding of such phenomena in terms of mechanisms and theory. Special emphasis centers on the study of cellular systems and tissues (e.g., nerve and retinal tissue) that may be particularly sensitive to electromagnetic and paramagnetic effects. A facility for exposing small animals is being developed. Preliminary data have been obtained in a study of effects of strong (1–4 kilogauss) static fields on growth and development in two different test systems (an insect and a mold).

Also in progress at LBL is an epidemiological study of some 2000 scientists and technicians who have been exposed to over 4000 "gauss days" per year for at least five years.

A range-finding study of biomagnetic responses in animal and cellular systems was recently initiated at the Pacific Northwest Laboratories. Work is getting underway on the study of magnetic field effects on growth, development, behavior, and other endpoints in mice and trout. Possible mutagenic effects, clastogenic action (alteration of chromosome patterns), modification of nerve function, altered cell growth, and other responses will be investigated in simpler test systems.

Genetic effects of static magnetic fields in two well-standardized test systems, Drosophilia and Tradescantia (a flowering plant), are being investigated in a study at the Brookhaven National Laboratory.

Question. Are you aware of the work of Marino and Becker at the VA Hospital in Syracuse, New York?

Answer. Yes. Both ERDA staff and contractors are familiar with the relevant scientific publications of Drs. Marino and Becker as well as their testimony before the New York State Public Service Commission during the recent licensing hearings on two 765 kV transmission lines (Cases 26529 and 26559). One of the purposes of ongoing studies at the University of Rochester and the Pacific Northwest Laboratories is to evaluate specific experiments that Dr. Marino has previously conducted and reported.

Question. How much money does ERDA plan to spend on non-ionizing radiation research next year?

Answer. It is planned to initiate at least two studies of electric-field bioeffects in fiscal year 1978. Some expansion of research on biomagnetic effects is also anticipated. In addition, several studies sponsored by the Bonneville Power Administration (Department of Interior) will be added to the above-described program as both ERDA and BPA become a part of the Department of Energy. The ongoing BPA research includes field studies to evaluate impacts of HV AC and DC lines on nearby biota and ecosystems as well as efforts to quantify electric fields, ion densities, and ion currents associated with DC lines. Summarized below are current ERDA projections for fiscal year 1978 (with fiscal year 1977 figures included for comparison):

[In thousands of dollars; fiscal years]

	Funding	
	1977	1978
Electric field studies:		
ERDA/EES	1,000	2,640
ERDA/BER	[1]210	[1]626
ERDA/ECT	33	49
Subtotal	1,243	3,315
Magnetic field studies: ERDA/BER	550	900
Total support	1,793	4,215

[1] Includes 70 in EPA pass-through funds.

Question. Is ERDA's research being coordinated with EPA?

Answer. Yes. As mentioned above, ERDA and EPA are cooperating in the funding and/or management of three research projects. In addition, the ERDA staff interacts in other ways with the technical staff of EPA's Office of Radiation Programs. A representative of that Office is a member of the Interagency Advisory Committee on Electric Field Effects from High Voltage Lines, which is chaired by Mr. Robert W. Flugum of ERDA/EES. Additional interactions occur at meetings sponsored by the Office of Telecommunications Policy, at scientific meetings, and by telephone or visits.

Question. During the hearing, you indicated a decision to transmit solar energy from space to earth via microwaves would require a considerable increase in research to study the effects of microwave radiation. Does ERDA have plans to conduct a study on this subject?

Answer. Yes. Representatives of NASA and ERDA have been working together for about eighteen months to develop a joint program for assessing the feasibility of NASA's concept of solar energy utilization based on a satellite power system (SPS), whereby solar energy collected in space would be transmitted to earth via a large microwave beam for subsequent conversion to electricity. As a result of this interaction, a detailed, two-volume "SPS Concept Development and Evaluation Program Plan" was completed in May 1977 and subsequently formally approved by the heads of both agencies. Pursuant to subsequent discussions and negotiations handled by representatives of the solar energy program, approval for implementation of an ERDA study resulted and a modest effort has been initiated.

Question. If so, what are the time frame and scope of the investigation?

Answer. It is planned to conduct a joint NASA/ERDA SPS concept development and evaluation program. According to the detailed plan that has been developed, a comprehensive study of the SPS concept will be conducted beginning in mid-FY 1977 and culminating late in FY 1980 in a go-or-no-go decision on program continuation into a second major phase, NASA's so-called technology advancement (hardware development) phase. NASA and ERDA have mutually agreed that the three-year assessment will encompass three major functional activities, as follows: (a) systems (i.e., hardware) definition, (b) space-related technology, and (c) environmental, socioeconomic, and comparative evaluation. It has been further agreed that NASA will have principal responsibility for the work dealing with systems definition and space-related technology whereas ERDA will carry lead responsibility for assessments concerned with environmental factors, socioeconomic issues, and comparative evaluations.

The Division of Solar Energy (SOLAR) has been assigned overall responsibility and authority for directing ERDA's participation in the joint SPS program. Budgetary authority also resides with SOLAR. In conducting SPS-related activities, the SOLAR staff is assisted by technical representatives from ERDA's Division of Technology Overview (TO) and Division of Biomedical and Environmental Research (BER).

Major elements in the planned ERDA SPS-related program are outlined below:

- Assessment of Environmental Factors:
  - Terrestrial operations
  - Launch, flight, and recovery operations
  - Space operations
  - Microwave impacts
- Assessment of Socioeconomic Issues:
  - Resource utilization
  - Economics/energy balance
  - Institutional/international factors
- Comparative Evaluations:
  - Terrestrial alternatives to SPS
  - Comparison (methodology, data base, and comparative assessment)

At the present time, BER representatives are responsible for managing three ongoing contracts for preliminary assessments of specific needs to resolve issues related to microwave effects on human health; biota and ecosystems; the atmosphere; and navigation, communication, radioastronomy, and electronic devices.

Question. Is this research coordinated with the National Aeronautics and Space Administration?

Answer. Yes. This activity has been closely linked with the NASA program from the very start. All planning activities have been coordinated with NASA through the NASA Office of Energy Programs, and a similar pattern of interaction is expected to continue throughout the three-year implementation phase.

Senator STEVENSON. Our next witness is Mr. Grover Wrenn, Deputy Director for the Health Standards program of the Occupational Safety and Health Administration.

STATEMENT OF GROVER WRENN, DEPUTY DIRECTOR, HEALTH STANDARDS PROGRAMS, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR; ACCOMPANIED BY BENJAMIN W. MINTZ, ASSOCIATE SOLICITOR OF LABOR; AND JOHN O'NEILL, DIRECTOR OF THE OFFICE OF PHYSICAL AGENTS STANDARDS

Mr. WRENN. Thank you.

Senator STEVENSON. I would be happy to put your full statement in the record so you could summarize.

Mr. WRENN. With me this morning on my right is Mr. Benjamin Mintz, Associate Solicitor of Labor for Occupational Safety and Health. On my left, Mr. John O'Neill, Director of OSHA's Office of Physical Agents Standards.

In the interest of time, Mr. Chairman, since the agency has recently responded to the committee's request for information in advance of the hearing, and we have submitted a statement, I would be happy to dispense with the reading of that statement or even a substantial summary of it and submit to any questions you have.

Senator STEVENSON. Thank you. Are you going to dispense with all statements?

Mr. WRENN. I would be happy to do that. Perhaps it would be useful if I note briefly that the Occupational Safety and Health Act of 1970 created the Occupational Safety and Health Administration. Our broad charter is to establish standards and enforce them to provide for the safety and health of American workers.

Radiation, both ionizing and nonionizing, is but one of the many aspects of worker safety and health that OSHA deals with. Additionally, as you know and have heard in the testimony of other agencies appearing before the committee, there are many other programs relating to radiation safety and health in the workplace for which other agencies have long had some regulatory responsibility. Therefore, OSHA is but one part of the overall Federal and State regulatory activity in providing for radiation safety and health programs in the workplace.

The statement does treat in some detail the relationship between OSHA regulatory programs and those that exist under NRC in particular and at the State level under both OSHA and NRC agreement plans.

I think those are the principal aspects of the statement.

Senator STEVENSON. Do you believe that the standards for exposure to radiation that you have to enforce are adequate, that the standards were derived from an adequate data base and that they adequately address the hazards associated with all forms of exposure to radiation in the workplace?

Mr. WRENN. I am not confident that that is the case. First of all, the scope of our regulations as presently established is quite broad in that OSHA regulations apply to any and all sources of ionizing radiation exposure, whatever that source may be, especially to the extent that it is not subject to regulatory authority of the NRC. However, the standards—the substance of the regulations that we enforce is derived entirely from long-established regulations issued originally by the AEC, adopted then under the Walsh-Healey Public Contracts Act by the Department of Labor to apply to employees of Federal Government contractors and then adopted without change under the provisions of the Occupational Safety and Health Act from the Walsh-Healey Public Contracts Act.

I would say to you that the substance of those standards has, at least in the experience of OSHA, not undergone review for the adequacy or protections they afford during the 6 years we have been in existence and of course many years prior to that while they were administered by other agencies.

Senator STEVENSON. Why haven't they been reviewed? How did OSHA accept the adequacy of them in the first place?

Mr. WRENN. The Occupational Safety and Health Act provided under section 6(a) of the act that during the first 2 years that the act was in effect the Secretary of Labor would promulgate as Federal Occupational Safety and Health Standards without administrative rulemaking all existing Federal safety and health standards and national consensus standards. That was the manner in which the Congress envisioned the agency would establish its initial body of safety and health standards on which to begin operation. As such, the substantial body of radiation safety standards that had been developed under the AEC and existed under the Department of Labor as part of the Walsh-Healey Safety and Health Standards were adopted without comment and without review.

That was the case with the entire body of initial safety and health regulations established by OSHA.

Since that time, Mr. Chairman, the very limited technical resources of OSHA in the standards-setting area have been largely consumed in focusing on new and more recently identified worker health hazards, particularly chemical carcinogens such as vinyl chloride, asbestos, arsenic, benzene and other such substances.

Simply as a matter of priorities, we have not had the luxury, so to speak, of looking backward at that initial body of regulations that we adopted when the act was first promulgated.

I will indicate to you, however, in recent efforts to expand the professional capabilities of the agency in the standards-setting area, particularly in the health area, we have established a new office of physical agents standards which is just at this moment beginning to be staffed. One of the major purposes of that office will be to review our existing body of standards for both ionizing and nonionizing radiation and in cooperation with our sister research agency, the National Institute for Occupational Safety and Health, from whom you will hear later, review existing evidence as to the adequacy of our standards and move as necessary to amend them.

Senator STEVENSON. Are the resources of NIOSH adequate?

Mr. WRENN. I think they will be speaking on that issue in their testimony.

Senator STEVENSON. For review of the standards?

Mr. WRENN. I have no reason to believe that they are not.

Senator STEVENSON. How long will this review take?

Mr. WRENN. We have placed little or no demands on them in that area because as I mentioned, the focus of our rulemaking activity has just not been directed toward the subjects of radiation in recent years.

Senator STEVENSON. Have you ever inspected workers exposed to radiation in a coal-fired generating plant?

Mr. WRENN. I seriously doubt it. I have looked at our records of enforcement activity at the Federal level under our radiation safety standards and the number of such inspections is limited. I did not identify the kinds of facilities in which those inspections were conducted. I would doubt very seriously.

Senator STEVENSON. You would have the authority to do so; would you not? Wouldn't that be within your jurisdiction?

Mr. WRENN. If it were a private enterprise, yes, it would be.

Senator STEVENSON. You noted in your statement that OSHA had conducted 28 inspections for ionizing radiation health hazards during fiscal 1976. That confirms what you are saying. It certainly sounds like a minimum effort. What kind of inspections were those?

Mr. WRENN. Those were most likely inspections of a general occupational health nature in a work place during the course of which some question of radiation protection was discovered. It is possible that the inspection was specifically related to a question of radiation safety, but with the knowledge of our field activities, generally, I would expect that those questions would have arisen in an inspection of a broader scope than simply radiation.

Senator STEVENSON. Can people who operate airport baggage scanners and passengers exposed to those scanners be assured that they are not being exposed to excessive ionizing radiation? Do you take steps to protect the people who operate those scanners?

Mr. WRENN. The Occupational Safety and Health Regulations would apply to employees engaged in the inspection processes. They would not apply in a consumer protection sense to passenger personnel. I did have an opportunity to review the statement that will be presented later by the National Institute for Occupational Safety and Health. I believe they refer to a recent survey of such baggage inspection equipment which they assisted in evaluating the safety of.

Senator STEVENSON. What about OSHA? Did it inspect these facilities?

Mr. WRENN. Our regulations could be applied in that area. Again, I know of no specific circumstances when we have done so. I suspect as a matter of practice at the present time, because of our focus on a number of other health issues, that it would not likely—we would not likely conduct such an inspection except in response to an employee complaint.

Senator STEVENSON. Well, this committee has been receiving employee complaints. One employee that we are aware of has questioned her employer. She questioned him repeatedly about acceptable radiation levels but never received an answer. The employees who man these scanners are given no advice or warning about the level of radiation to which they are exposed. They are given dosimeter fountain pens, but they apparently get mixed up and different persons wear the same pens, so the pens reveal little if anything about each person's exposure.

They receive no indication of the levels of radiation to which they have been exposed. The employees in the early stages of pregnancy receive no special attention.

What you are saying then is that they have to complain before OSHA will protect them?

Mr. WRENN. I am saying as a matter of practice, because of the limited number of health compliance officers that we currently have for the entire country, the number of work places that we have responsibility for conducting inspections in, and the current focus of the agency on such health hazards as lead and mercury and chemical carcinogens that is not likely in the normal course of events that we would inspect for that hazard, although we have very distinct procedures for responding to employee complaints.

In the normal course of events, were we to receive an employee complaint about such matters, we would undoubtedly respond with an inspection.

Senator STEVENSON. Don't you think in the normal course of events this is something that should be looked at even with your limited resources?

Mr. WRENN. Mr. Chairman, I could agree to an affirmative response to that question about a number of subjects in the occupational health field, including ionizing radiation.

Senator STEVENSON. Well, we would urge you to do that and would be very interested in finding out what the results of your look are.

We have heard of a NIOSH report which apparently concludes that as many as four out of five industrial radiation incidents go unreported. Is OSHA attempting to coordinate with BRH's incident radiation registry to rectify this situation?

Mr. WRENN. We have a close working relationship with the Bureau of Radiological Health. We do receive the incident reports from BRH. I think we share that general perception that even with specific reporting requirements, there is substantial underreporting of such incidents.

Senator STEVENSON. The EPA has indicated that OSHA won't cooperate with the Interagency Task Force on Occupational Exposure Standards. How do you respond to that?

Mr. WRENN. I am sorry. I didn't understand your question.

Senator STEVENSON. Apparently EPA has indicated that OSHA would not cooperate with an Interagency Task Force on Occupational Exposure Standards. That task force is reviewing and adopting standards. If this is true, why doesn't OSHA cooperate?

Mr. WRENN. Mr. Chairman, I am unaware of any opportunity which OSHA has had to cooperate with the EPA in which we declined to do so. I would be glad to look into that.

Senator STEVENSON. I would appreciate that.

Thank you very much.

We have more questions, but we will take the liberty of following up in writing.

[The statement follows:]

STATEMENT OF GROVER WRENN, DIRECTOR OF HEALTH STANDARDS PROGRAMS FOR THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTATION

Mr. Chairman and members of the committee, I thank you for the opportunity to appear today and discuss the response of the Occupational Safety and Health Administration (OSHA) to the challenge of controlling workplace radiation hazards. Accompanying me today is Benjamin W. Mintz, Associate Solicitor of Labor for Occupational Safety and Health.

OSHA has the responsibility of assuring, so far as possible, that all employees in the Nation are provided with safe and healthful working conditions by their employers. Under the Occupational Safety and Health Act of 1970, covered employers have the general duty to provide a place of employment free from recognized hazards likely to cause death or serious physical harm. In addition, the Act provides a specific obligation that such employers comply with job safety and health standards issued by OSHA. In administering this law, OSHA conducts workplace inspections to assure compliance with these obligations. When OSHA's compliance officers discover violations during an inspection, employers may be issued appropriate citations, civil monetary penalties may be proposed and periods for correcting the alleged violations are established.

Any of thesse may be contested before the Occupational Safety and Health Review Commission, an independent adjudicatory body established to hear such appeals, OSHA also pursues a program of consultation, information, and education to assist and encourage those employers seeking to comply with the law.

Section 18(b) of the OSH Act affords each State the opportunity to submit a plan which would allow the State to assume responsibility for occupational safety and health matters. The State's program must be at least as effective as the Federal program. OSHA closely monitors the implementation and progress of each State plan to assure its continued effectiveness, and may withdraw its approval and resume Federal jurisdiction if the State plan fails to fulfill its commitment to implement and administer an equally effective program. Presently, 24 States are implementing plans which have been approved by the Secretary of Labor under section 18(b).

In discussing OSHA's specific responsibility for workplace radiation hazards, let us first examine the scope of the problem. In general, ionizing radiation is any radiation capable of producing ions by interaction with matter. X, gamma, alpha, beta and neutron are the radiation types of primary concern to OSHA because of their frequent presence in the occupational environment. The potential for exposure to ionizing radiation is especially great among certain workers including medical and dental personnel, industrial radiographers, food processors, materials handlers and equipment service personnel.

While the effects of high level exposure have been known for years, the effects of lower level radiation have not fully been observed. The body's response to the assault of radiation differs from one individual to another depending on a number of factors, including the tissues affected, one's age at the time of exposure and the irradiation energies to which one is exposed. OSHA, therefore, recognizes the desirability of establishing standards which adequately assure employee protection.

Section 6(a) of the OSH Act provided for the adoption as the OSHA standards of any established Federal standards which were in force at the time of enactment. OSHA adopted as radiation standards, and continues to enforce, those promulgated under the Walsh-Healey Public Contracts Act. The OSHA radiation standards are found at 1910.96 and 1910.97 of Title 29 of the Code of Federal Regulations. As further background, these Walsh-Healey standards were modeled on those developed by the Atomic Energy Commission whose authority is now vested in the Nuclear Regulatory Commission (NRC) and the Energy Research and Development Administration (ERDA). Therefore, OSHA's radiation standards and those of NRC are essentially the same.

The NRC and OSHA standards, although virtually the same, do not, however, apply to the same situations. NRC's statutory authority is limited to coverage of those radiation sources emanating from three categories of material known as source, byproduct, and special nuclear materials. A number of so-called other sources of radiation, for example, X-ray machines, naturally occurring materials such as radium, electron miscroscopes, particle accelerators and airport baggage scanners, are outside the purview of NRC.

The OSH Act comprehensively covers every employer who is engaged in a business affecting commerce and who has one or more employees. The Act contains no express limitations on this coverage nor any express general exemptions. However, it does contain provisions designed to avoid duplication of effort between OSHA and other agencies with statutory authority to promulgate standards or regulations affecting occupational safety and health. Under section 4(b)(1) of the Act, OSHA does not apply to working conditions addressed by other Federal agencies standards or regulations affecting occupational safety and health. Thus, OSHA applies its requirements, including its radiation standards, to those radiation working conditions not addressed by NRC's standards. Specifically, this means that OSHA applies to working conditions where employees are exposed to "other sources" since there is neither coverage nor applicability over these sources under NRC standards.

While the jurisdictional lines between OSHA and NRC are clear, another jurisdictional arrangement involving the States requires some explanation. Even before the enactment of OSHA, certain States entered into licensing agreements with the AEC pursuant to section 274 of the Atomic Energy Act of 1974, as amended (42 U.S.C. 2021), under which it was determined that these "agreement States" would be allowed, to regulate "other sources" of radiation in the interest of providing workers with the fullest protection. OSHA has allowed these States to continue their regulation of these "other sources" provided the Assistant Secretary of Labor determines that the States' programs are compatible with the OSHA radiation regulations. In these States employers registered and licensed under a State-NRC agreement program are considered to be in compliance with OSHA radiation standards. The Assistant Secretary's determination is facilitated by an annual letter from the Nuclear Regulatory Commission to the Assistant Secretary of Labor setting forth assurances that the States' programs are compatible. OSHA's current rationale for continuing such an approach is the preservation of State jurisdiction in areas which the States have long been regulating in a manner consistent with Federal radiation standards. In addition to regulating "other sources" because they have an agreement with NRC, States may also be operating an OSHA approved State plan which must contain radiation standards identical to or at least as effective as Federal OSHA standards.

Such State OSHA standards likewise contain provisions for accepting employer compliance with State-NRC agreement regulations as compliance with State OSHA radiation standards. Often States utilize the same technical staff for "NRC agreement" and "OSHA State plan" radiation enforcement through a system of referrals.

Another Federal agency with radiation safety and health responsibilities is the Energy Research and Development Administration. ERDA controls facilities which are government owned and contractor operated (GOCO's). The Atomic Energy Act expressly provided for the promulgation of standards to protect the workers in these government owned facilities from workplace hazards including, but not limited to, radiation hazards. To implement that statutory authority under the Atomic Energy Act, AEC (now ERDA) agreed to issue all the OSHA standards. Those standards are now applicable to all private employers working in GOCO facilities regulated by ERDA. By operation of law ERDA, not OSHA, is responsible for the enforcement of these standards. These circumstances were recognized in a letter between the Secretary of Labor and the AEC in 1974.

One final Federal agency with which OSHA shares concern for radiation hazards is the Food and Drug Administration's Bureau of Radiological Health (BRH). A Memorandum of Understanding between the two agencies was signed in 1974 in which OSHA and BRH agreed to establish uniform standards for regulating electronic products, our concern being those used in the workplace. Also included in that agreement are provisions which require that each agency notify the other should any suspected violations of the agency's standards be discovered during routine inspections.

OSHA radiation compliance activity during fiscal year 1976 consisted of 28 inspections for ionizing radiation as well as 25 microwave inspections and four inspections involving lasers.

OSHA will continue to work with the Federal and State agencies which I have mentioned in order to ensure that workers are afforded protection from the hazards of radiation. I will now be happy to answer any questions the Committee may have.

[The following information was subsequently received for the record:]

U.S. Department of Labor,
Occupational Safety and Health Administration,
Washington, D.C., December 1, 1977.

Hon. Warren G. Magnuson,
Chairman, Committee on Commerce, Science and Transportation, U.S. Senate, Washington D.C.

Dear Mr. Chairman: This is in response to your September 13, 1977, letter in which you requested that I answer a number of additional questions following the Committee's oversight hearings on radiation health and safety. My answers to these questions are enclosed and, as you requested, I have submitted five copies of my responses to your Committee staff under separate cover.

Please excuse the delay in responding to your request. If I can be of further assistance, please contact me.

Sincerely,

Grover Wrenn,
Director, Health Standards Programs.

Enclosure.

Question 1. Please submit to the Committee a time schedule for the proposed review by OSHA of ionizing and non-ionizing radiation standards and the date when revised standards are expected to be issued.

Response. The process of reviewing existing standards for ionizing and non-ionizing radiation is a continuing one, as it is for all safety ad health standards, and the Occupational Safety and Health Administration (OSHA) is currently performing staff work on its ionizing and non-ionizing radiation standards. However, at the present time, there is no specific timetable for the issuance of revised radiation standards. OSHA must set priorities which ensure that the greatest number of workers receive protection from the most serious occupational safety and health hazards. OSHA is currently attempting to establish a realistic schedule for the completion or revision of those standards which deserve the greatest attention. A listing of the safety and health standards which merit the highest priority for future rulemaking was recently submitted to the U.S. District

Court for the District of Columbia. This listing was submitted as part of a report required by the Court in *Usery* v. *National Congress of Hispanic American Citizens*. The listing reflects our best judgment of OSHA's rulemaking priorities, and a copy is enclosed for your information. The exclusion of radiation standards from this listing in no way is meant to imply that OSHA considers the hazards of radiation unimportant. Rather, it simply reflects our belief that OSHA's resources may be better utilized by concentrating our standards-writing efforts in areas where either no standards exist, or where existing standards do not provide adequate protection from the hazards they address.

Coverage of workers exposed to the hazards of radiation continues to be provided by a comprehensive OSHA ionizing radiation standard under 29 CFR 1910.96. In addition, OSHA has requested that the National Institute for Occupational Safety and Health provide its recommendations concerning a future OSHA standard for microwave radiation and other forms of electromagnetic radiation.

HEALTH STANDARDS PRIORITIES OSHA WORKPLAN FOR JULY 1977 TO JANUARY 1978

Hazard domain	Priority factors (exposure; effects; evidence)	Project status
Diving	2,000 to 2,500; decompression sickness and trauma.	Published.
Arsenic[1]	10,000; lung cancer; scientific literature and research; animal studies; epidermiology.	Draft final standard under agency review.
Cancer policy[1]	Millions; special attention to serious health problems.	Draft proposal under review by solicitor.
Labeling[1]	Millions; right to know workplace hazards	Research continuing.
Cotton dust[1]	700,000; bysinosis, chronic obstructive, lung disease; scientific literature and research; epidermiology.	Record of rulemaking being evaluated prior to preparation of final draft standard.
Benzene[1]	200,000 to 1,000,000; leukemia, blood dyscrasis; scientific literature and research; animal studies; epidemiology.	ETS issued May 1977; hearings July 1977; final standard November 1977.
Standards completion project—Toxic substances.	Millions; establish permissible exposure limits.	6 ketones; draft of single standard for 400 toxic substances under review.
Lead	1,200,000 to 5,300,000; lead intoxication, "subclinical" effects, susceptible groups, rate retention; scientific literature; animal studies; epidemiology.	Record of rulemaking being evaluated prior to preparation of draft final standard.
Emergency temporary standard (ETS).	Unknown; serious health effects; as available.	To answer unscheduled crisis as it evolves.

HEALTH STANDARDS PRIORITIES OSHA WORKPLAN FOR JANUARY 1978 TO JULY 1978

Beryllium	Several thousand; beryllium disease, lung disease; scientific literature and research; animal studies; epidemiology.	Proposal ready; hearings scheduled to begin Aug. 16, 1977.
Noise	13,000; noise-induced hearing loss; scientific literature and research; animal studies; epidemiology.	Proposal ready (need staff assistance to evaluate record).
Pesticides	360,000 (manufacturing and fabrication); attacks various body functions, lungs, etc.; scientific literature and research; animal studies; epidemiology.	Research continuing.
Skin dermatitis	Millions; dermatitis sensitization absorption/systemic toxicity; workers' compensation; lost work days; scientific literature; medical experience.	Advisory commission being reformed.
Abrasive blasting	84,000 to 200,000; acute silicosis/other toxic dusts; scientific literature and research; animal studies; epidemiology.	Draft proposal being developed.
Confined spaces	Millions; suffocation or exposure by inhalation to toxic gases and vapors combined with physical hazards of difficult entry/egress; scientific literature and research; animal studies; epidemiology.	Research continuing.
Chromates	15,000 to 25,000; cancer; scientific literature and research; animal studies; epidemiology.	Draft proposal ready for agency review.
Chlorinated solvents (trichloroethylene [TCE], perchloroethylene [PCE] methyl chloroform).	Millions; narcosis (acute) possibly carcinogenic; scientific literature and research; animal studies; epidemiology.	Proposal for TCE published Oct. 20, 1975.
Emergency temporary standard (ETS).	Unknown; serious health effects; as available.	In response to emerging evidence.

[1] Proposal or final rule will be published by January 1978.

Notes: (1) Health standards priorities will be evaluated every 6 mo since rapid changes in OSHA knowledge of hazards occur frequently. Resources have been earmarked above for a high-priority substance which may be handled as emerging temporary standards (ETS). (2) New health standards for sulfur dioxide, TDI/MDI and asbestos will be reconsidered at this time.

Question 2. What changes do you contemplate in those standards? What will be included in your data base?

Response. While OSHA has established no specific timetable for revision of its radiation standards, staff work is being performed to study the scope of any possible changes in these standards. A discussion of these efforts follows.

A. Ionizing Radiation

1. Changes

A revision of OSHA's ionizing radiation standard, 29 CFR 1910.96, is under development at the present time. One purpose of this effort is to achieve consistency in the protection provided by OSHA and other Federal agencies. It is anticipated that certain technical definitions would be revised to conform with those now commonly accepted in the professional community. In consideration of the efforts of both national and international standards activities, the issue of whether or not to accept a black color radiation warning symbol (as an alternative to the purple symbol) on a yellow background is being considered. OSHA's efforts at revising its ionizing radiation standard also include the consideration of: new labeling provisions applicable to x-ray equipment; a radioactive materials inventory reporting provision; requirements for specific radiation protection interlocks and posting requirements for facilities containing x-ray equipment; new radiation survey requirements; and some changes to the reporting and record-keeping requirements. It is anticipated that property damage alone will no longer be a reason for making a report to OSHA under any future revision of the standard.

As with practically all radiation protection standards and guidance, including those of the Federal Radiation Council and the former Atomic Energy Commission, the primary data base is composed of the recommendations from the National Council for Radiation Protection and Measurements and the International Commission on Radiation Units and Measurements. Secondary data bases include regulations and standards of the Nuclear Regulatory Commission, the Food and Drug Administration, the American National Standards Institute (ANSI), the Department of Transportation, and the model regulations of the Conference of State Radiation Control Program Directors.

B. Laser Radiation

1. Changes

OSHA's current standard for laser radiation, 29 CFR 1926.54, is applicable solely to the use of lasers in the construction industry. Our current efforts to revise this standard would extend its applicability to general industry, shipbuilding, and agriculture. Provisions on labeling, eye protection, posting, and interlocks would be required as the relative laser radiation hazard potential increases.

OSHA is reviewing a number of reports, suggestions, standards and recommendations on laser safety and bioeffects in the study of this standard. The primary data base is the ANSI laser safety standard. A number of standards are also being reviewed and analyzed for rationale and effectiveness in providing the intended degree of safety. These include the laser standards and recommendations prepared by the U.S. Army Environmental Hygiene Agency, the British standards organizations, and the Bureau of Radiological Health (BRH). We are also utilizing the Laser Classification Guide, which was prepared by the U.S. Army Environmental Hygiene Agency and published by the National Institute for Occupational Safety and Health. This guide, prepared at OSHA's request, contains technical information on approximately 2,500 different model lasers that have been manufactured.

Question 3. On page 75 of the transcript, Dr. Rowe, Deputy Assistant Administrator for Radiation programs for EPA, mentioned an interagency group which examines appropriate standards for occupational radiation exposures. There is some question as to the extent of cooperation by OSHA and other agencies in this effort. Please explain any misunderstandings EPA and OSHA are having in working together within this interagency framework. What caused them? Have they been resolved?

Response. The Environmental Protection Agency (EPA) has a broad mandate to protect the general public and the environment from radiation exposures. OSHA, on the other hand, has jurisdiction over occupational radiation exposures from such sources as x-ray machines and accelerator produced and naturally occurring radioactive materials. To the extent permitted by its statutory authority and resources, OSHA has cooperated with the EPA Interagency Committee to protect workers from radiation hazards. Despite this cooperation, there have been apparent limitations to the effectiveness of this arrangement.

Early this spring, OSHA, EPA, the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA) agreed that improvement in the overall coordination by regulatory agencies responsible for safeguarding worker and public health was needed. In early August, these agencies, working in concert, began planning to streamline their regulatory processes and to maximize their resources. As a result of this effort, on September 26, 1977, OSHA, EPA, CPSC and FDA entered into an interagency agreement relating to the regulation of toxic and hazardous substances which includes radiation control.

The objectives of this agreement are threefold: (1) to make the most efficient use of resources, (2) to achieve consistent regulatory policy, and (3) to improve the protection of the environment and of worker and public health. To meet these objectives, the agencies will coordinate: regulations where a hazard can be most effectively controlled by joint participation; compliance and enforcement procedures and policies; research and development policies; methods of obtaining, analyzing, storing, and exchanging information which could be of mutual interest; and public communication and education programs. Furthermore, the four agencies have established interagency communications channels to facilitate the exchange of information and to explore options for increasing cooperation and coordination.

Under this interagency agreement, a Regulatory Development Workgroup has been formed to study and make recommendations about regulatory problems common to two or more of the agencies. One of the topics to be studied by the workgroup is ionizing radiation, and a specific subgroup has been formed for this purpose with the Food and Drug Administration as the lead agency.

Question 4. Are OSHA's radiation protection guides merely advisory or are they mandatory? What is the status of the *Swimline Corporation* case?

Response. Section 6(a) of the Occupational Safety and Health Act of 1970 (the Act) provides that during the first two years following the effective date of the Act, the Secretary of Labor shall ". . . promulgate as an occupational safety and health standard any national consensus standard . . . unless he determines that promulgation of such a standard would not result in improved safety and health. . . ." One national consensus standard incorporated under section 6(a) was the American National Standards Institute (ANSI) C95.1–1966, which was promulgated as OSHA's non-ionizing radiation standard, 29 CFR 1910.97. The term "radiation protection guide" contained in the OSHA standard, therefore, had its source in the ANSI standard.

29 CFR 1910.97(a)(1)(iii) defines "radiation protection guide" as the "radiation level which should not be exceeded without careful consideration of the reasons for doing so." In the *Swimline Corp.* case, an administrative law judge for the Occupational Safety and Health Review Commission (the Commission) ruled that 1910.97(a)(2)(i), which sets forth the radiation protection guide limits, is advisory rather than mandatory because 1910.97(a)(1)(iii) states that the limits "should" not be exceeded. The Secretary of Labor had originally requested that the Commission review this case, but subsequently withdrew this request since it was likely that 29 CFR 1910.97(a)(1)(iii) could not have been enforced in this particular case. The administrative law judge's decision thus became a final order of the Commission.

1910.97(a)(1)(iii) specifies that the employer is not required to follow the "radiation protection guide" as long as "careful consideration" is given to reasons for deviating from the guide. No specific criteria have been established as to what constitutes "careful consideration." In *Swimline*, the employer established "careful consideration" criteria which were not rebutted by the Secretary. Had the Secretary determined that the employer failed to follow the radiation protection guide without giving "careful consideration," a citation for violating 29 CFR 1910.97(a)(2)(i) would have been proper.

It should be emphasized that the Secretary's position in the *Swimline* case was based upon the specific facts of that situation not upon the word "should" contained in the standard. It is the Department of Labor's position that "should" standards are mandatory. This position is derived from the definition of an OSHA standard (section 3(8) of the Act) and the mandatory duty of all employers to comply with such standards (section 5(a)(1) of the Act).

Question 5. Are you aware that NIOSH field studies indicate that 75 percent of the workers using radio frequency sealing and heating equipment were found to be exposed to radiation levels higher than the present occupational standard? When and how did you receive such information from NIOSH? How have you responded to these findings? What is currently being done to protect these workers?

Response. OSHA has received no information from the National Institute for Occupational Safety and Health (NIOSH) to indicate that there are adverse health effects associated with the use of radio frequency radiation equipment at the levels of exposure presently encountered. Although OSHA does recognize the fact that the proliferation of industrial radio frequency equipment constitutes a potential occupational health problem, OSHA must obtain more complete bioeffect and exposure data as a basis for the development of an occupational health standard. These data will help us facilitate our evaluation of occupational exposures to radio frequency radiation; and to this end OSHA has requested that NIOSH provide us with its recommendations, perhaps in the form of a criteria document. OSHA could then use these recommendations in the promulgation of a future radio frequency standard.

Question 6. Laser devices are finding increasing use in many areas of our society, including the workplace. How extensive are OSHA's activities in this area?

Response. As indicated in our response to Question 2, OSHA currently has standards applicable to the use of lasers in the construction industry in 29 CFR 1926.54. These standards provide for qualified laser operators; mandates safe work practices, including personal protective equipment, warning signs and equipment labelling; and set limits for employee exposure. During Fiscal Year 1976, 74 violations of 1926.54 were cited by OSHA.

While staff work has begun on a new laser standard with a wider range of industrial applications, no specific date for promulgation of this new standard is yet available.

Question 7. How serious is the problem of excessive exposure to ironizing radiation for medical and dental personnel, industrial radiographers, food processors, materials handlers, and equipment service personnel? Are these people being routinely monitored to determine cumulative radiation dose, and to allow follow-up studies of future health effects?

Response. OSHA ionizing radiation standards (29 CFR 1910.96) require that all employers covered by the Occupational Safety and Health Act of 1970 (the Act) take precautionary measures to ensure that no employee is overexposed to ionizing radiation in the workplace. These measures include the requirement that personal monitoring equipment be provided for each employee who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable maximum permissible exposure limits. 1910.96 also mandates even stricter monitoring requirements for individuals under 18 years of age, and establishes detailed reporting procedures to be followed by employers whenever any overexposures do occur.

The problem of overexposure to ionizing radiation within occupational groups, such as health care and food processing, is very difficult to assess. Overexposure data, to the best of our knowledge, is not ordinarily collected or classified by occupational categories. However, data collected by the Nuclear Regulatory Commission, the Armed Forces and certain State agencies indicate that the vast majority of employees monitored for exposure to radiation are within existing exposure limits.

Question 8. Does OSHA have responsibility for protecting research students and faculty at universities employing radiation devices such as x-ray machines and lasers? If so, how is this responsibility being carried out? If not, whose responsibility is this?

Response. While OSHA comprehensively covers all private employers, Congress included section 4(b)(1) in the Act to avoid duplication of effort among Federal agencies. Section 4(b)(1) provides, in effect, that the Act may apply to all working conditions except those particular working conditions for which another Federal agency promulgates enforceable standards affecting occupational safety and health. But, even under the limitations of section 4(b)(1), the Act applies to all covered employers using x-ray and laser equipment since no nother Federal agency has preempted OSHA from applying to such equipment. The Act covers all employers, except Federal, state and local governments. Therefore, all covered employers, including private universities, must comply with OSHA requirements related to job safety and health protection for all employees utilizing x-ray and laser equipment.

In certain states OSHA indirectly provides job safety and health protection to public university employees through funding to the states. Section 18(b) of the Act allows each state to assume responsibility for its own occupational safety and health program. When a state program is determined by the Secretary of Labor to be at least as effective as the Federal program, it is Federally funded on a matching basis. Among other requirements of section 18, the state program must provide job safety and health protection for public employees in the state. Therefore, public university employees in those states with their own occupational safety and health programs approved by the Secretary of Labor would be provided protection.

Students, as the term is generally understood, are not considered "employees" for OSHA purposes. However, if a covered employer—a private college, for example—is in compliance with OSHA standards, the employer's workplace is thereby made safer for *all* those who occupy the workplace, whether they be faculty members (employees) or students. This would also be the case under state 18(b) programs applicable to both public and private universities in the state.

Question 9. Please document your assertion that the protection of airport baggage inspectors from excess radiation by x-ray scanners lies within the jurisdiction of OSHA. If this is the case, why have no inspections of this equipment been made?

During the oversight hearings, Senator Stevenson called your attention to the complaints he had received with respect to the safety of airport baggage scanner operators. These included: the improper use of dosimeter "fountain pens," rendering their measurement value meaningless; lack of action on the part of employer and OSHA despite repeated complaints and questions from one employee; and the complaint that pregnant employees receive no special attention. What has the agency done since these allegations were brought to your attention?

What plans do you have in the future to ensure that airport baggage scanners are not reaching excess levels of ionizing radiation and that safety standards are being observed?

Response. As discussed in our response to Question 8, section 4(b)(1) of the Act provides that the Act applies to all working conditions of private employers except those particular working conditions for which another Federal agency promulgates enforceable standards affecting occupational safety and health. While the Food and Drug Administration's Bureau of Radiological Health (BRH) does regulate the *emissions* from machines such as airport x-ray baggage scanners, its authority does not include the regulation of employee *exposure* to such equipment. Therefore, since no other Federal agency has preempted OSHA's application to the particular hazard of employee exposure to emissions from x-ray baggage scanners, the Act, by virtue of section 4(b)(1), applies to this particular hazardous working condition.

When the Federal Aviation Administration proposed that baggage scanning equipment be used for airport security purposes, OSHA assisted BRH in developing guidelines to eliminate unnecessary occupational and public exposure to emissions from these devices. These guidelines were published in the *Federal Register* on August 8, 1973. To evaluate the effectiveness of these guidelines, BRH inspected new equipment both at the manufacturing plants and at the airports after installation. The National Institute for Occupational Safety and Health, in response to a request for technical assistance, conducted studies to determine the effects of product design and work environment on employee exposure. OSHA, in its regulatory role, also responded to a number of employee complaints about scanning equipment.

Present regulations for the protection of employees from exposure to emissions from scanning devices do not differentiate between pregnant females and other employees. It is believed that no significant risk for pregnant employees exists when current standards for equipment design and operation and standards for worker protection are followed.

As priorities permit, OSHA will continue to inspect airports and evaluate employee exposure to x-rays as a part of baggage scanning activities. (OSHA inspection priorities are noted in the response to Question 10.)

Question 10. During the hearings you indicated that the 28 inspections which OSHA conducted in FY '76 for ionizing radiation hazards were made during the course of general health hazard inspections. Is it the opinion of OSHA that potential radiation health hazards are not considered a high enough priority to merit inspections for this purpose alone? Do you have plans to intensify your inspection program in this area?

By what criteria does OSHA determine the need for inspections? Are all facilities inspected periodically? How frequently are inspections made? How large an inspection force does OSHA have? How many inspectors are there from the states? Is the indicated number of inspections adequate to assure compliance with OSHA regulations and to assure the safety of workers? If additional funding were available to increase your inspection capability, what funds would be required to assure reasonable compliance?

Response. OSHA recognizes the great potential health problems associated with the use of radiation in the workplace. However, our limited inspection resources must be utilized in a manner which the greatest number of employees from the most severe hazards. In order to accomplish this end, the enforcement of standards is conducted within the context of a set of overall inspection priorities. These are, in order: response to reports of imminent danger; investigation of workplace fatalities and catastrophies; response to employee complaints of workplace hazards; generally scheduled inspections directed to workplaces in industries with known health hazards or high injury frequency rates; and areas of special emphasis. These priorities are designed to focus the Agency's attention on the most serious threats to worker well-being.

At our current rate of inspection, OSHA's 1435 Federal compliance officers would inspect about 2 percent of the nation's workplaces per year.

There are also 998 state inspectors conducting investigations in the 25 states or jurisdictions with their own occupational safety and health programs. From these figures, it is clear that OSHA must rely heavily on voluntary compliance of employers to assure safe and healthful workplaces. Although additional personnel would undoubtedly result in an increase in the number of inspected workplaces, it would be impossible to give a realistic figure of how many inspectors we require to assure "reasonable compliance."

Question 11. You agreed that as many as 80 percent of industrial radiation incidents go unreported. In order to encourage reporting of radiation incidents, do OSHA and BRH need additional authority to assess stronger sanctions against non-complying employers? What other measures should be taken to encourage compliance with reporting producers?

Response. The Agency feels that the Act provides sufficient sanctions against employers who do not comply with OSHA's regulations dealing with recordkeeping and reporting requirements. OSHA may impose civil penalties of up to $1,000 for other-than-serious violations and up to $10,000 for willful or repeateed violations of its recordkeeping and reporting regulations. As a further safeguard, section 17(g) of the Act provides that "Whoever knowingly makes any false statement, representation, or certification in nay application, record, report, plan, or other document filed or required to be maintianed pursuant to this Act shall, upon conviction, be punished by a fine of not more than $10,000 or by imprisonment for not more than six months, or by both."

Apart from recordkeeping, the Act contains other sanctions. Penalties of up to $1,000 per day may be imposed on employers who fail to correct violations discovered during an OSHA investigation. Mandatory civil penalties are applied in the case of serious violations; these may be up to $10,000. In imminent danger situations the Secretary of Labor may petition the district court to restrain an employer from continuing an unsafe practice. We feel that stronger sanctions than these are unnecessary.

OSHA's best method for assuring compliance with its regulations, in addition to its enforcement activities, is educating employers and employees about their responsibilities under the Act. One method OSHA employs in achieving this end is providing on-site consultative advice to employers through contracts with the states. This consultation, provided at the request of the employer, is available free-of-charge in 38 states and jurisdictions, and utilizes the states' personnel as consultants. Under this type of program, employers may discover problems in their workplaces and learn exactly what their responsibilities are under the Act.

OSHA also provides educational assistance to employers and employees through special programs designed to assist in the recognition, avoidance and prevention of unsafe and unhealthful working conditions, including those hazards posed by radiation. Two current training programs, for example, include radiation hazards as part of their curricula whenever the target audience may be exposed to radiation in the workplace. One of these programs is designed for apprentices and the other for union officials.

Question 12. In your prepared comments, you state that "OSHA also pursues a program of consultation, information, and education to assist and encourage those employers seeking to comply with the law." What is the current funding level for this program and what fraction of the business community does it reach? What efforts are being made to improve this program?

Response. During Fiscal Year 1977, OSHA budgeted approximately $1 million for education purposes. At this funding level only 0.1 percent of the employers and employees covered by OSHA received direct instruction under our educational programs. In order to reach more individuals, OSHA is developing a new strategy which will focus our educational efforts on employer and employee "peer group" organizations such as unions, trade associations, educational institutions, etc. rather than on employers and employees directly. The purpose of this strategy is to develop internal educational competence within these peer group organizations, and thereby increase the number of individuals receiving instruction. Additionally, OSHA's education budget for Fiscal Year 1978 has been raised to $3 million.

On-site consultation is currently available in 24 states and jurisdictions which operate their own safety and health programs under section 18(b) of the Act. Additionally, under section 7(c) (1) of the Act, OSHA has entered into contracts with 14 other states and jurisdictions in which their personnel are utilized to provide consultative advice free-of-charge to requesting employers. $12 million has been budgeted for these 7(c) (1) consultation programs for Fiscal Year 1978, and it is estimated that 20,000 consultative visits will be made. In order to further encourage states and jurisdictions to enter into 7(c) (1) contracts, the level of Federal funding for this purpose was recently increased from 50 to 90 percent of the program cost.

OSHA's public information program is operated by the national office, utilizing a variety of means, such as *Job Safety and Health* magazine, news releases and general information publications. The overall information budget for Fiscal Year 1978 is $670,000, a significant portion of which is used to inform employer and employee organizations about current occupational safety and health matters. The October 1977 issue of *Job Safety and Health*, for example, contains an article entitled "Radiation Safety in Industry." A copy of this magazine is enclosed for your information.[1]

Question 13. You state that under section 4(b) (1) of the OSH Act, OSHA "does not apply to working conditions addressed by other Federal agencies or regulation affecting occupational safety and health." If EPA were to promulgate an occupational exposure standard for non-ionizing radiation, would such a standard preempt OSHA's jurisdiction in the area?

Response. OSHA has interpreted section 4(b) (1) of the Act to mean that the Act applies to all working conditions except those for which another Federal agency promulgates enforceable regulations affecting occupational safety and health. Should EPA promulgate a standard for non-ionizing radiation, OSHA, by application of section 4(b) (1), would be preempted from applying to non-ionizing radiation hazards to the extent the particular hazard to employees in the workplace may be eliminated or reduced under the EPA standard. However, such a situation under section 4(b) (1) is not common, since EPA's statutory authority deals with problems affecting the environment and the public generally; OSHA's statutory authority is specifically directed to workplace hazards encountered in the employment context.

Question 14. Both BRH and EPA share with you some jurisdiction over either exposure or emission standards with respect to radiation emitted from medical equipment. How are these programs coordinated?

Response. An interagency agreement between OSHA, EPA, the Food and Drug Administration (including BRH) and the Consumer Product Safety Commission was signed September 26, 1977. The purpose of this agreement is to foster cooperative efforts among the participating agencies in their regulation of toxic and hazardous substances. Under this agreement, a Regulatory Development Workgroup has been formed to study and make recommendations about regulatory problems common to two or more of the agencies. One of the topics to be studied by the Regulatory Development Workgroup is ionizing radiation, and a specific subgroup has been formed for this purpose with the Food and Drug Administration as the lead agency. We are optimistic that the efforts of this subgroup will lead to more efficient use of the agencies' resources, the formation of consistent regulatory policies, and an improvement in the protection of the public's health and environment from the hazards of radiation.

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[1] Retained in committee files.

An earlier memorandum of understanding between OSHA and the Food and Drug Administration provided for cooperative efforts between OSHA and BRH in establishing consistent Federal standards relating to electronic product safety, and in determining compliance with these standards. Although the cooperative efforts under this memorandum have been largely superseded by the more recent four-agency agreement, a number of contacts between OSHA and the BRH were made at the staff levels of both agencies.

Question 15. Dr. Harris of NIOSH indicated that OSHA has jurisdiction over uranium mining operations because it is a natural source of radiation. Please refute or support this statement, with citation to relevant statutes.

Response. Prior to the President's signing of the Federal Mine Safety and Health Amendments Act of 1977 on November 9, 1977, the Department of the Interior's Mining Enforcement and Safety Administration (MESA) had primary jurisdiction over safety and health conditions in uranium mining operations. The Federal Metal and Nonmetallic Mine Safety Act was the statutory basis for this authority.

Under the new Mine Safety and Health Amendments Act of 1977, MESA functions and personnel will be transferred to the Department of Labor on the effective date of the Act—March 9, 1978. Under the new law, a Mine Safety and Health Administration, within DOL, will have jurisdiction over mining, including uranium mines.

As noted in our response to Question 8, section 4(b)(1) of the Occupational Safety and Health Act of 1970 (the Act) was provided to avoid duplication of effort among the Federal agencies. Under section 4(b)(1), the Act applies to all working conditions of private employers except those particular conditions for which another Federal agency promulgates enforceable standards affecting occupational safety and health. Since uranium mining operations are covered by the regulations of another agency, OSHA, by application of section 4(b)(1), is largely preempted from applying to these operations.

Question 16. Does the Administration support proposals such as Senator Randolph's bill which would set federal minimum standards for licensing radiologic technicians?

Response. The Administration has not yet announced its views on Senator Randolph's bill—S. 1695, the Radiation Health and Safety Act of 1977.

Senator STEVENSON. Our next witness will be Dr. Elliott S. Harris, Director, Division of Biomedical and Behavioral Science, National Institute for Occupational Safety and Health, accompanied by a number of other witnesses.

STATEMENT OF DR. ELLIOTT S. HARRIS, DIRECTOR, DIVISION OF BIOMEDICAL AND BEHAVIORAL SCIENCE, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH; ACCOMPANIED BY DR. WORDIE H. PARR, CHIEF, PHYSICAL AGENTS EFFECTS BRANCH; WILLIAM E. MURRAY, CHIEF, RADIATION SECTION; AND DR. ZORY R. GLASER, DIRECTOR, SPECIAL HAZARDS EVALUATION PROGRAM

Dr. HARRIS. Thank you.

Senator STEVENSON. Thank you.

Dr. HARRIS. I am afraid Dr. Glaser stepped out for a moment. He will be in shortly.

Mr. Chairman, I am Dr. Elliott S. Harris, Director of the NIOSH Division of Biomedical and Behavioral Science.

We are pleased to have been invited to discuss the NIOSH programs relating to occupational exposure to radiation. We have discussed in a separate letter the four specific questions Senator Magnuson raised in his letter of May 26.

The National Institute for Occupational Safety and Health, NIOSH, was established by the Occupational Safety and Health Act of 1970—Public Law 91-596. Prior to 1970, the predecessor organization of NIOSH operated under the general research authorities of the Public Health Service Act.

Between 1968 and 1971 a small portion of our resources were devoted to the radiation effort. Following passage of the act, NIOSH was given specific responsibility to develop recommended standards for exposure to a broad range of occupational hazards, including radiation. A radiation section was established in 1972 in the Physical Agents Effects Branch of NIOSH.

We do not have authority under the Radiation Control for Health and Safety Act of 1968—Public Law 90-602—which concerns the public health aspects of radiation emissions from electronic products.

However, under the Occupational Safety and Health Act, NIOSH has several vital functions related to occupational safety and health. These include the conduct of research programs, the performance of hazard evaluations, field studies, morbidity and mortality studies, the development of recommended standards, the dissemination of information to employers and employees, the provision of technical assistance, and the conduct of training and education programs. Many of these are concerned specifically with ionizing and nonionizing radiations.

The development of criteria documents as a basis for standards for occupational exposure to chemical and physical hazards is a continuing activity of NIOSH. These criteria documents are prepared for the purpose of recommending an occupational health or safety standard to OSHA within the Department of Labor, which is responsible for setting and enforcing standards to protect workers.

It is the goal of the Institute to identify the health effects produced by a substance or process and to recommend methods to evaluate and control the hazard. Before the documents are transmitted, they undergo extensive internal review and external review by management and trade associations, organized labor, academia, State and Federal agencies and professional societies.

More than 60 criteria documents recommending standards for occupational exposure have been transmitted to OSHA, including documents on hot environments and ultraviolet radiation. Documents involving consideration of worker radiation exposure planned for completion during fiscal years 1977 to 1981 include radio frequency—(RF)—and microwave radiation, infrared radiation, and ultrasonic radiation. In addition, a criteria document will be developed for welding and brazing processes, which have radiation exposure aspects.

One of NIOSH's major efforts mandated by Congress is the study of industrial carcinogens. Since it is well established that ionizing radiation induces cancer in man, NIOSH has initiated a study to survey the current knowledge of radiation-induced carcinogenesis. The information will assist us in estimating the potential carcinogenicity of the various forms of radiation and help to update the National Academy of Sciences 1972 summary report entitled, "The Biological Effects of Ionizing Radiation."

For the past decade, NIOSH and its predecessor organizations have been gathering, analyzing, and publishing epidemiologic data on the hazards to workers from radon daughter products present in the uranium mining and milling operations. It was this work which first identified the lung cancer problems among uranium miners. Efforts were initiated to control exposure, and a cohort of exposed workers is currently being followed as part of our surveillance activities. This research on uranium miners was also instrumental in developing field methods for measuring radon daughters, procedures for engineering controls, and medical monitoring procedures for the diagnosis of lung cancer.

NIOSH has provided technical assistance, upon request, in addressing problems from radiation-generating equipment. For example, because of employee concern for the possibility of excessive ionizing radiation exposure, the FAA and the ATA requested NIOSH to evaluate the potential exposure radiation hazards to airport personnel working with baggage X-ray inspection units. This is the study to which Mr. Grover Wrenn referred.

NIOSH performed this service, and concluded that the employee doses were well below the OSHA exposure standard, and that the radiation hazard was minimal.

A large part of NIOSH present and future radiation effort is the nonionizing area. Our efforts include programs on visible, infrared, optical, ultraviolet, laser, radiofrequency/microwave radiation and ultrasonic radiation.

NIOSH transmitted a criteria document on ultraviolet radiation—UV—to the Department of Labor in 1972. In addition to recommended occupational exposure standard, the document addressed environmental data, bioeffects, quantitative measurements, and protection and control measures.

I would like to add here as a comment that all our criteria documents do this. They not only address the standards, but they address control factors as well.

The UV portion of the spectrum is responsible for sunburn, and can produce eye damage. Prolonged exposure to UV radiation results in hyperpigmentation and the possibility of skin cancers. Another less common effect of ultraviolet radiation on normal skin causes the victim to develop freckling, depigmentation, precancerous tumors, basal and squamous cell cancers, and malignant melanomas. Welding arcs, certain sun tanning lamps, and industrial lamps and dryers can emit large amounts of UV radiation and have the potential of producing these effects in workers.

The following areas were identified in the ultraviolet criteria document as requiring further research effort: the lack of a portable survey instrument for evalulating UV hazards according to the recommended standard. That is a survey instrument which could be carried into the workroom and used there.

We also studied the need for research on the ocular effects over the wavelength range of 315 to 400 nanometers.

Portable UV monitors have been developed and are presently undergoing testing and evaluation. The National Bureau of Standards cooperated in developing an ultraviolet transfer standard, and in establishing at NIOSH a UV calibration facility. Research is also underway to determine UV thresholds for ocular effects in the 300–400 nanometer range.

In the infrared radiation area, although the near-IR portion of the spectrum has been implicated in the development of cataracts, threshold levels have not been established as a function of wavelength. NIOSH will soon initiate studies to assess eye damage resulting from exposure to such near-IR radiation. These data will be used to assist in the development of an occupational exposure standard.

In the area of lasers, in fiscal year 1968 we surveyed over 2,100 lasers in 200 occupational establishments in three States: Massachusetts, New Jersey, and California. The protocol included a review of the company safety program, and a "walk-through" survey of the laser operating area. The safety and engineering control procedures were found to be marginal or inadequate for 40 percent of the lasers in use.

In fiscal year 1975 NIOSH was requested by OSHA to prepare a compendium of lasers which would categorize lasers into one of five hazard classes specified in a recent draft of the OSHA proposed standard for exposure to lasers.

The report was compiled with the assistance of the U.S. Army Environmental Hygiene Agency and was published in 1976. The compendium contains technical data on 2,500 laser devices manufactured after 1963.

With the inception of the Federal energy conservation program, questions were raised about the health and safety implications associated with reduced illumination levels in the workplace. At the direction of the Secretary of HEW, NIOSH sponsored a symposium on the subject and invited experts in the field of illumination from the United States and Europe to present their views. Based on the information available, NIOSH concluded that the only effect on health from reduced illumination levels in the workplace would be an increased occurrence of eyestrain and that there was no evidence for any long-term permanent ocular damage.

With regard to safety, it was concluded that the standard used by the General Services Administration would not pose an additional hazard to worker health and safety. The proceedings of the symposium were published as a technical report.

Additional projects have been pursued which involve an integrated approach to evaluating optical radiation hazards. This includes the ultraviolet, visible, and IR spectrum.

We are performing a study in conjunction with the American Welding Society to examine hazards of the welding process. Optical radiation measurements have been made by NIOSH and the U.S. Army Environmental Hygiene Agency on the most common welding processes, under a variety of conditions.

We are also determining whether transparent welding curtains surrounding the welder protects his coworkers from harmful levels of optical radiation. At the request of the Newspaper Guild, we have performed surveys to measure the radiation emissions from the cathode ray tube of video display terminals used in a newspaper composition room where two young employees developed bilateral cataracts. The levels of optical and RF radiation measured were several orders of magnitude below the existing occupational exposure guidelines, and it has not been possible to establish that the cataracts are related to radiation emissions from these terminals.

NIOSH has developed a calibration and testing facility to assist in evaluating optical radiation hazards. This facility contains several standard sources and detectors for the calibration of laboratory and field instruments.

We have also initiated a quality assurance program to perform long-term studies on the stability, accuracy, and reproducibility of the instruments.

Continuing our discussion of the radiofrequency and microwave radiation area, workers are potentially exposed to RF and microwave radiation from a large number of sources and devices, including a large number of radio and radar transmitters, industrial drying, heat sealing and curing equipment, and certain medical research devices.

Consequently, NIOSH is planning a criteria document for occupational exposure to RF and microwave radiation. NIOSH is currently updating an extensive bibliography of world literature of the bioeffects of RF and microwave radiation.

Recent observations raise the question of this possibility of cancer induction by TACAN radar, which is extensively used for tactical air navigation. NIOSH was requested to investigate the work hazards associated with TACAN and TACAN repair at DOD facilities following the filing for worker's compensation of the surviving one of two TACAN repairmen who had been diagnosed as having carcinoma of the pancreas.

At none of the three survey sites did the measured levels of microwave or X-radiation exceed the currently accepted permissible exposure levels.

NIOSH is also considering performing a retrospective epidemiologic study to determine whether TACAN system repairmen exhibit an increased incidence of cancer of the pancreas, as well as carcinomas of other body sites.

NIOSH became aware of several problem areas in the radiofrequency radiation band, specifically 10–300 megahertz, in 1972. The first problem to be recognized was that employers often were unaware that they were using RF radiation in their facilities. This may have stemmed from the fact that the industrial uses of RF generators were not widely publicized, and little information was available on their uses.

For this reason, estimates of workers exposured to RF and microwave radiation vary from as few as 50,000 to as many as 21 million.

The second problem identified was that there were no survey instruments available with which "near zone" measurements could be made in the field. Third, little information was available on the biological effects at the radio frequencies used in industry.

The National Bureau of Standards laboratory in Boulder, Colo., has developed, under interagency agreement with NIOSH, RF-detection equipment capable of measuring the energy in the "near-zone" of the electromagnetic field, as is the case of the worker exposure situations we have studied.

A unique RF exposure and calibration facility capable of simulating near-field exposure conditions was also developed for NIOSH by NBS. This facility has been used to evaluate commercial monitoring instrumentation which manufacturers claim to be usable from 10 to 40 megahertz. Accurate measurement equipment and instrumentation, and standard survey techniques are essential for the monitoring and enforcement of RF and microwave exposure levels.

In our field studies 75 percent of the workers using RF sealing and heating equipment were found to be exposed to RF radiation levels higher than the present occupational exposure guideline. A majority of these workers were females of child-bearing age. Because recent literature indicates that exposure of pregnant animals to RF radiation may harm the fetus, we have started animal studies designed to determine threshold levels for effects from RF exposure.

Various NIOSH divisions provide support and training functions in the radiation field. NIOSH has been responsible for the calibration of instrumentation used by the OSHA compliance officers in inspections of the workplace. The Maintenance and Calibration Laboratory has established calibration procedures and techniques for ionizing radiation and microwave survey instruments. These instruments are routinely calibrated on a 12-month cycle. A radio frequency radiation calibration facility is in the final stages of development and will be completed by the end of 1977.

NIOSH presents short-term training courses in occupational safety and health as part of its responsibilities for manpower development. The courses provide the health professional with an overview of industrial hygiene and safety as well as specialized training to broaden the background of the practicing professional.

Two of the specialty courses address the safety and health problems associated with ionizing and nonionizing radiations. Course materials are available to any Federal or State agency and other interested groups. The general availability of these courses serves as a multiplying factor in enhancing the NIOSH role in training and manpower development.

Mr. Chairman, this concludes our overview of NIOSH's involvement in the occupational aspects of radiation health effects and worker protection.

If you have any questions, my colleagues and I will be glad to try to answer them.

Senator STEVENSON. Thank you, Dr. Harris.

You say that more than 60 criteria documents recommending standards for occupational exposure have been transmitted to OSHA. How many of these standards have been adopted by OSHA?

Dr. HARRIS. At the present time the ones on asbestos, vinyl chloride, coke oven emissions, and a group of 13 chemicals shown to be carcinogens, have been adopted. There are 10 to 12 currently in the rulemaking process. So we are talking about a handful that have been adopted, and 10 to 12 more in the rulemaking process.

Senator STEVENSON. Out of 60?

Dr. HARRIS. Out of 65; yes, sir.

Senator STEVENSON. What happens to the others?

Dr. HARRIS. They are still being reviewed within OSHA. OSHA must go through a public hearing process.

Senator STEVENSON. Does OSHA have the adequate resources with which to review these criteria documents?

Dr. HARRIS. I cannot address that. I do not know.

Senator STEVENSON. What are the major sources of exposure by workers to ultrasonic radiation?

Dr. PARR. There are a number of them which I could identify at this time. Probably one of the most widespread is the jet plane. The Navy has expressed concern about women flight directors for landing aircraft, some of whom may be pregnant.

Other groups include outside workers at airports. We have had a request from Pittsburgh to look into a situation where there is an increased number of cardiac or related problems.

Dr. HARRIS. Ultrasonic devices are used extensively in industry for cleaning and for welding. They are also used medically for diagnosis of cancers and for locating and determining the position of the human fetus. There are a wide number of uses for ultrasonics.

Senator STEVENSON. Are there standards and are they in force now with respect to ultrasonic radiation?

Dr. HARRIS. There are no standards for industrial use of ultrasonic radiation.

Senator STEVENSON. What about the research with respect to infrared radiation?

Dr. HARRIS. Infrared is used extensively for drying and heating purposes. It is used for everything from drying to lamination of wood.

Dr. PARR. I want to add that the welding process gives off ultraviolet, visible, and infrared radiation.

Senator STEVENSON. Are there standards in this instance?

Dr. HARRIS. No, sir.

Senator STEVENSON. What are the major sources of exposure to radiofrequency radiation?

Mr. MURRAY. There are numerous applications, based upon the ability of RF radiation to cause objects to heat. We do have a list of applications that we can enter into the testimony.

Senator STEVENSON. I would be glad to have it.

Senator STEVENSON. You say NIOSH is beginning studies to determine threshold levels for effects of radiofrequency exposure. How long are those studies going to take? Do the workers exposed in the meantime have any protection?

Dr. HARRIS. The studies are longtime studies. One does not expose a single animal and hope to get any usable results. These are going to be fairly extensive studies which will be repeated at a variety of wavelengths, and durations of exposure using phantom models, as well as animals. We anticipate that it will be a minimum of 3 to 5 years before we have usable results. In the meantime, there are no standards.

Senator STEVENSON. You say that field studies—your field studies, 75 percent of the workers using RF sealing and heating equipment were found to be exposed to RF radiation levels higher than the present guidelines?

Dr. HARRIS. That is right. These are guidelines, not standards.

Senator STEVENSON. Let us take microwave radiation. What are the principal sources of worker exposure to microwave radiation?

Mr. MURRAY. Again, we are talking primarily about heating and drying applications, in the food processing industry, textile industry, plastics industry, forest products industry, and others.

There are also ovens which are undoubtedly used in commercial establishments.

They are also used for medical diathermy.

Senator STEVENSON. Any standards yet in the case of microwave radiation?

Mr. MURRAY. The present OSHA regulation does cover the frequency range from 10 megahertz up to 100,000 megahertz. This includes both the radiofrequency radiation and the microwave radiation areas. We do not feel that the guidelines below 300 megahertz in the RF range has been studied adequately to evaluate the possible human effects so as to assume that the guideline is valid. In fact, measurement in terms of power density using units of milliwatts, in which the standard is written is meaningless in the radiofrequency range.

Senator STEVENSON. How do you expect to change the 10 milliwatt standard?

Mr. MURRAY. What was the question?

Senator STEVENSON. Let me ask the staff to ask the question.

Ms. NELSON. Can you speculate on what changes you will make in the present occupational exposure standard with respect to nonionizing radiation? Can you predict how the microwave standard might be changed?

Mr. MURRAY. I think primarily with what we know now, the radiofrequency band between 10 and 300 megahertz will be the part which is most likely to be changed, simply because it is written in the wrong terminology.

It should be in terms of the electric field strength, volts per meter, and the magnetic field strength, amps per meter, which the current American National Standards Institute (ANSI) standard adopted.

Going back to the fact there is very little biological-effects information available in the RF region, it is difficult to speculate whether the 10 milliwatt per square centimeter ($10mW/cm^2$) value is valid, or which way it will change, if it does change. The possibility of a recommended change, or the direction of change in the microwave region is also unknown at this time.

Ms. NELSON. When will the criteria document be published?

Dr. HARRIS. The RF/Microwave criteria document is scheduled to be published in fiscal year 1979. During that period, we will have an input in terms of some of the work which we have done. If additional information becomes available after the document is transmitted to OSHA, the document will be updated if necessary.

Senator STEVENSON. What are the major sources of worker exposure to ionizing radiation?

Mr. MURRAY. The three major sources are X-ray type devices, which includes industrial radiography and several other types of nondestructive testing; accelerators used for research and nondestructive testing, and radionuclides such as radium radon sources.

In terms of radionuclide sources, radium radon sources are primarily used for inspection purposes.

Senator STEVENSON. Does OSHA or NRC have responsibility for protecting workers in the uranium mining and milling fields from radiation?

Mr. HARRIS. That would be MESA, sir.

Senator STEVENSON. And the same would apply to coal mines?

Dr. HARRIS. I believe that would be true.

Senator STEVENSON. What do we know about exposure to radiation in coal mines?

Dr. HARRIS. At the present time, very little. We are doing some work on coal conversion, coal gasification and liquefaction. During the course of reviewing what is known about these processes, we have come up with the observation that a potential hazard could exist from the presence of radioactive material in some mines, or in the coal. Therefore, we are developing, as part of a program under EPA sponsorship, the control technology involved in reducing that potential radiation hazard to workers.

Senator STEVENSON. And the radiation comes from coal in gasification and liquefaction?

Dr. HARRIS. There is a possibility of the release of the radiation, or radioactive materials, in the gasification and liquefaction processes.

Senator STEVENSON. Not from the burning of gas and coal, but from the conversion of the coal to the oil and gas?

Dr. HARRIS. I cannot answer that. We do not know what would be residual in the gas or coal.

Senator STEVENSON. I thought you said earlier that it was released during the conversion process, not from the burning process.

Dr. HARRIS. That is right. We need to distinguish between the burning or combustion of coal, and conversion processes.

Senator STEVENSON. But it could come from the burning, too, if there is residual radioactivity in the oil that results from the burning of coal?

Dr. HARRIS. That is right.

Senator STEVENSON. But it does occur during the conversion?

Dr. HARRIS. That appears to be possible.

Senator STEVENSON. I was unaware of that. I had heard in the burning of the coal, radioactivity is emitted. Is there a worker-exposure problem in that event also?

Dr. HARRIS. This may very well be. This is what we are looking into.

Senator STEVENSON. That will be part of the study?

Dr. HARRIS. That is right.

Senator STEVENSON. Any——

Dr. HARRIS. As it applies to the workers, not as it applies to the general population.

Senator STEVENSON. Well, that ought to produce a lot of information and it might have broader implication.

When will this study be concluded?

Dr. HARRIS. I do not have that information right now.

Senator STEVENSON. Sometime after we have made the decision to convert to coal?

[The following information was subsequently received for the record:]

One gasification project was started in June 1976, another has just been initiated and is scheduled for completion during 1980. Preliminary work on the liquification project has begun. It is scheduled for completion during 1979.

Senator STEVENSON. What is the current personnel and funding level for NIOSH's efforts with respect to nonionizing radiation?

Dr. HARRIS. Currently, in the total radiation area, our total budget for fiscal year 1978 is approximately $360,000.

Senator STEVENSON. You mentioned a lack of a portable survey instrument for evaluating ultraviolet hazards. Have you been handicapped by the lack of such instruments for measuring other sources of radiation?

Dr. PARR. Yes; very much so.

Senator STEVENSON. And in OSHA?

Dr. PARR. OSHA probably has the same problem. One of the problems we have encountered is the lack of appropriate equipment to measure the near-field RF exposure levels. This has also limited the research which is necessary in this area.

After identifying the problem our first effort was to develop survey equipment under interagency agreement with the National Bureau of Standards. We have used this equipment in our surveys. We have also collaborated with OSHA, making measurements when requested. The one piece of equipment that is on the market now is the magnetic field detector. The electric field detector is still awaiting development.

Senator STEVENSON. The problem is not one of resources, it is just that the equipment has not been developed?

Dr. PARR. That is right. The equipment has not been developed. In the ultraviolet area, we have tried to develop a meter that would respond according to the standard recommended in the NIOSH criteria document. The exposure limits are wavelength-related. The meter we had developed was an excellent one. It worked very well, but could not be produced commercially.

We have since tried to develop and improve a second meter, which we are presently evaluating. This particular meter is a portable meter that could be placed in front of any ultraviolet source, and would read out the exposure level for all the different wavelengths with appropriate biological weighing.

All you would have to do would be to look at the table—developed as part of the meter—to determine the permissible exposure time.

Senator STEVENSON. Is industry responding to this need by developing other kinds of equipment to determine exposure?

Dr. HARRIS. Mr. Chairman, in many cases it is not a question of the lack of funds or the lack of desire. It is the lack of technology.

Senator STEVENSON. That is what we are getting at. That is what I am asking. Is it coming onstream. Is industry developing the technology?

Dr. Harris. With stimulation, it is; yes.

Senator Stevenson. With stimulation?

Dr. Harris. Yes.

Senator Stevenson. Where is the stimulation coming from?

Dr. Harris. Two sources.

No. 1, a requirement that there be such an instrument.

The other is the feeding of the development; feeding it by requiring or requesting that it be developed.

Senator Stevenson. Can you require them to develop?

Dr. Harris. Well, if this was a standard, you cannot have a standard unless—

Senator Stevenson. I understand that. I gather in some instances, as you have indicated, there are not true standards but rather guidelines.

Dr. Harris. That is right.

Senator Stevenson. In those I would assume there is not an overwhelming tendency to provide the equipment. From what you say, at least, a lot of the equipment has not been developed. The incentives apparently have not been there.

In those cases, to the extent they still exist, are the resources available with which to go out and buy the technology and develop it under contract?

Dr. Harris. In some cases, and not in others.

Senator Stevenson. There are not sufficient resources, in other words?

Dr. Harris. No; it is not a matter of not sufficient resources. Not sufficient technology.

Senator Stevenson. What I am referring to is the resources with which to contract for the development of that technology.

Dr. Harris. I cannot answer that. I do not know what resources are necessary.

Dr. Parr. I think you can see we have had an excellent relationship with the other Federal agencies in the development of our equipment.

Senator Stevenson. Well, gentlemen, you have been very patient. We are running late. I may need to follow up with some written questions.

Thank you, gentlemen.

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Ocular Ultraviolet Effects from 290–400 nm—University of Houston.

Improving the Welding Environment—American Welding Society.

Dielectric Properties Measurements for RF (10–300 MHz) Phantom Modeling—Georgia Institute of Technology.

PAMPHLETS

Occupational Health Facts about Ultraviolet Energy.
Ultraviolet Radiation and the Work Environment.
Welding Safety.

SOME APPLICATIONS OF RF/MICROWAVE RADIATION IN INDUSTRY

Automotive

Heat-sealing: body interior trim panels, upholstery covers for seats and backs, convertible tops, drying of trim base panels, and embossing of heel pads to carpets.

Food Products

Finish-drying or "polishing" baked goods, melting chocolate prior to tempering, thawing frozen items, and inhibiting enzyme action.

Furniture-Woodworking Products

Plywood panel patching, lumber edge gluing, plywood or particleboard scarf gluing, laminated beams, veneer panel gluing, door lamination, ski lamination, and fiberboard fabrication.

Glass Fiber Products

Drying: glass fibers on forming tubes, roving packages, and coatings on continuously moving strands. Drying and curing sizing on machine packages.

Paper Products

Correcting moisture profile on continuously moving webs, heating coating on continuous webs, drying twisted twine packages, drying resin coatings, and gluing paper.

Plastic Heat-Sealing Products

Including: acetate box covers, advertising novelties, appliance covers, aprons, baby pants, beach balls, belts and suspenders, blister packages, book covers, capes, check book covers, charge cards, cushions, diaper bags, display boxes, electric blankets, equipment covers, food packages, fountain pens, garment bags, gas masks, goggles (industrial), hand bags, hat covers, index cards, lampshades, liquid containers, luggage, machine covers, mattress covers, milk cartons, oxygen tents, packages, pharmaceuticals, pillow cases, pillow packages, plastic gloves, pool liners, protective clothing, rain apparel, racquet and golf bags, refrigerator bags, shoes, shoe bags, shower curtains, slip covers, splatter mats, sponge backings, sport equipment, tobacco pouches, toys, travel cases, umbrellas, wallets, waterproof containers, and wire terminal covers.

Rubber Products

Preheating prior to molding and/or curing latex foams, and gelling and drying latex foams.

Textile and Fibers

Drying: rayon cake packages, wound packages, impregnated or coated yarns, slasher coatings, and continuous webs.

Other RF/Microwave Applications

Advertising—RF excited gas display signs.
Ceramics—dry ceramic items.
Chemical—activation of reactions.
Electronics—tube aging and testing.
Laser—RF-excited gas lasers.
Medical—diathermy and possible cancer therapy.
Scientific Equipment—low temperature ashing of samples.
Tobacco—dry blended tobacco and dry cigars.
Welding—RF stabilized welders.

[The following information was subsequently received for the record:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH,
Cincinnati, Ohio, October 6, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of September 13, 1977, requesting additional information concerning NIOSH's program in radiation safety and health. Enclosed are five copies of the responses to the Committee's twelve questions and an additional ten attachments providing detailed information.

NIOSH appreciated the opportunity to testify at the radiation oversight hearing and is pleased to submit the additional documentation requested by the Committee.

Sincerely yours,

ELLIOTT S. HARRIS, Ph. D.,
Director, Division of Biomedical and Behavioral Science.

QUESTIONS FOR DR. ELLIOT HARRIS, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Question 1. Please submit to the committee the following materials:

The FAA-sponsored study on baggage x-ray inspection equipment in which it was concluded that employee doses were well below the OSHA exposure standard.

Your prepared list of typical sources of exposure to workers from various forms of radiation.

A list of NIOSH publications concerning radiation.

Question 2. In your prepared comments the statement was made that "NIOSH has initiated a study to survey the current knowledge of radiation-induced carcinogenesis." How much of this information is available from other federal agencies? Does the NIOSH study represent a duplication of effort? Is not the BEIR report already being updated by others?

Question 3. During the Hearing, you stated that field studies have shown that 75% of the workers using radio frequency sealing and heating equipment were found to be exposed to radiation levels higher than the present occupational exposure guidelines. When were these measurements taken? How was this information transmitted to OSHA? Will efforts be undertaken to protect these workers pending completion of the study you mentioned?

Question 4. In response to a Committee question concerning FDA highlight achievements in radiation protection, the FDA states that with respect to airport baggage inspection units, it "began its investigation of the safety of these devices shortly after their introduction into U.S. airports in early 1973." The FDA reports it found excessive leakage and scatter radiation to operators and passengers being emitted by units and that it published an equipment performance standard applicable to airport baggage inspection units in 1974. Dr. Harris, in his pepared statement before the Committee, states that NIOSH evaluated "the potential radiation hazards to airport personnel working with baggage X-ray inspection units." In what manner did NIOSH coordinate its inspection of these baggage units with the FDA's BRH, particularly with respect to the FDA's equipment standard which was applicable to these units, and in light of the FDA's certification of the units for radiation safety?

You also stated that airport personnel working with baggage X-ray inspection units face a minimal radiation hazard. To what extent are these personnel routinely monitored for X-ray exposure? To what extent is equipment monitored for emission levels?

Question 5. How are you correlating your effort in setting a laser exposure standard with BRH's emission standards for lasers? When you state that the safety or engineering control procedures were found to be marginal or inadequate for 40% of lasers in use, what criteria were you using for making that judgment? Is there likely to be confusion on the part of users and manufacturers of lasers and laser products because of the difference between FDA and NIOSH on the matter of the number of classes into which lasers are divided?

Question 6. How serious is the problem of worker exposure to laser radiation at present? What should be done to minimize risk of overexposure in light of its increased use in the future?

Question 7. Please elaborate on the case of the young employees who developed bilateral cataracts after exposure to CRT and VDT. What is the statistical probability of cataract formation for employees of this age?

Question 8. On page 441 of the transcript you mentioned a retrospective epidemiological study which NIOSH may conduct to determine whether TACAN system repairmen exhibit an increased incidence of cancer, especially cancer of the pancreas. Assuming that your plans in this respect have now become more clearly defined, can you offer specifics about the study (i.e., expected duration, study design, budget) ? What is the probability of such cancer in men of the age of the two victims referred to above? Can you comment on the incidence of pancreatic cancer in the geographical area of Rhode Island? Is that entire area subject to more microwave exposure than is common in the rest of United States?

Question 9. You indicated the concern of NIOSH for the two TACAN system repairman who developed cancer of the pancreas. Paul Brodeur, in his December 1976 *New Yorker* article, claims that the Navy and NIOSH were less than responsive to allegations of a hazard associated with TACAN radar. Please submit your comments on this statement.

Question 10. Please cite the studies to which you alluded which "indicate that exposure of pregnant animals to RF radiation may harm the fetus."

Question 11. The Committee is interested in obtaining more information about the study NIOSH is seeking to sponsor on the radioactivity emitted during the burning of coal and during the conversion of coal via liquefaction and gasification processes. Do you have an idea as to when this study might take place and how soon conclusions might be made available to Congress?

Question 12. You state NIOSH established a radiation section in its physical agents effects branch in 1972. How many personnel does this section have, and what is its current funding level? In your opinion, are present funds adequate to carry out its assigned responsibilities? Do you think that it is necessary for NIOSH to have its own radiation section when ERDA, EPA, BRH, and others are currently involved in this area?

Answer 1. The report entitled "Documented Personnel Exposures from Airport Baggage Inspection Systems" is enclosed (Attachment A).[1] The study was sponsored by NIOSH at the request of the Air Transport Association (ATA) and coordinated with the FAA as mentioned in our testimony. Further discussion of the report can be found in the response to question four.

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[1] Document is available from Superintendent of Documents GPO, Washington, D.C. 20402, HEW publication No. (NIOSH) 77-105.

The Physical Agents Chapter from the NIOSH publication entitled "Occupational Diseases" (in press) is enclosed (Attachment B). The chapter emphasizes the bioeffects of radiation but also includes information on typical applications/occupations in which various types of radiation sources are employed (see pp. 471–2, 475–7, 478–9, 486–8, and 495). NIOSH has found this information more useful than a directory or compendium of industrial radiation sources. Also enclosed is information on the estimated number of workers potentially exposed to ionizing, optical or RF/microwave radiation (Attachment C). The potentially exposed population has been estimated for each occupational category employed by the Bureau of Census and extrapolated to 1980.

Attachment D is the list of NIOSH publications concerning radiation.

Answer 2. The NIOSH radiation carcinogenesis literature review was initiated in fiscal year 1976 to investigate the carcinogenicity of ionizing and nonionizing radiation under the NIOSH cancer initiative program. Under this project, the world literature concerning radiation-induced cancer was reviewed and summarized in a state-of-the-art report on radiation carcinogenesis. Studies reported between 1971–76 were emphasized but earlier literature was referenced when necessary.

The report identifies the radiation types which have been shown to be carcinogenic in humans or animals and discusses possible mechanisms, threshold levels, dose-response relationship and synergistic effects. For other radiation types, studies relating to their potential carcinogenicity are discussed. Gaps in knowledge of radiation carcinogenesis are identified and recommendations made for future research needs. The report is currently in the final draft stage and will be published in three volumes early in fiscal year 1978.

In preparing the review, the contractor employed all information sources at his disposal including reports from Federal agencies and the listing of current Federal projects maintained by the Smithsonian Scientific Information Exchange. However, as an indication of the information available from other Federal agencies, less than ten percent of the references cited in the report was from Government agencies.

The wide scope of the review dictated that it be done extramurally. Extensive discussions were held with the personnel of BRH and the National Cancer Institute to avoid duplication of effort. Both agencies reviewed the contractor's draft final report. Copies of the review are enclosed (Attachments E and F).

The NIOSH report assesses the carcinogenic potential from both ionizing and nonionizing radiation. The BEIR I report of 1972 was accepted as conclusive up to its date of publication. The NIOSH volume on ionizing radiation carcinogenesis emphasized studies published from 1972–1976.

A second BEIR report (BEIR II) authored by the National Academy of Sciences (NAS) was recently released by EPA. The BEIR II report addresses only "the problem of evaluation of the total benefits derived from exposure to ionizing radiations for comparison with the total risks" and made no attempt to update the bioeffects literature.

NIOSH has learned that EPA has recently requested NAS to update the BEIR I report. Copies of the NIOSH review have been provided to NAS to be used as a reference base for their update, and to avoid duplicating effort.

Answer. The measurements on the industrial RF sources, upon which the 75 percent figure is based, were done in FY 75–77. The results were not formally transmitted to OSHA because its regulation cannot generally be applied to the RF (10–300 MHz) radiation region. The power density units (10 mW/cm^2) used in the OSHA regulation cannot be employed in making valid RF personnel exposure measurements. NIOSH's measurements were compared to the ANSI C95.1–1974 occupational exposure guides. However, the ANSI standard has an inadequate basis in bioeffects and consequently is of little value in determining the adequacy of worker protection.

Answer 4. The baggage x-ray study as mentioned in question one above was requested by the airlines through the Airline Transport Association (ATA) in 1974 because of concern expressed by airport personnel and the threatened close-down of baggage x-ray equipment in major U.S. airports. The investigation included ten airlines at five major U.S. airports and evaluated the potential radiation hazard to personnel operating the baggage x-ray systems. Whole body and wrist badges were issued to 72 security personnel for two-week intervals and then processed. The maximum exposure reading obtained was equivalent to five percent of the OSHA standard for whole body exposure and one-half percent for hand-arm (extremity) exposure.

BRH was informed of the objectives of the study but it was felt that due to the occupational nature of the problem and the fact that BRH standards do not address this issue no further coordination was necessary. However, BRH was sent the draft final report for review and comments relative to their baggage x-ray performance standard. The results of this study indicated that the BRH standard is effective not only in reducing the x-ray exposure of the general public but also in minimizing the occupational exposure to airport security personnel.

The conclusion that security personnel are exposed to a minimal radiation hazard with the use of the baggage x-ray units is based on the result of the hazard evaluation by NIOSH personnel and the BRH emission standard. NIOSH has no information on personnel monitoring and survey programs employed by the airlines or FAA.

Answer 5. NIOSH is not planning to develop a recommended standard for occupational exposure to laser radiation. Over the last several years, NIOSH has consulted with OSHA on the development of a proposed regulation which to date has not been promulgated. The latest draft of the proposed OSHA standard showed the same number of laser classes as the FDA/BRH standard. The proposed OSHA standard does divide Class III lasers into two groups. The BRH makes the same provision but has not formalized it in its classification scheme.

An occupational health survey of lasers was done in FY 68-69 to define specific problem areas related to the use of lasers. The survey consisted of two parts: (1) an interview with management to obtain information relating to the plant, health and medical programs, safety, etc., and (2) a walk-through survey of laser areas to observe environmental conditions. The latter part of the survey focused on the availability and use of procedural/engineering controls including warning devices, controlled access, beam enclosure, interlocks, reflective surfaces, safety eyewear, and protective clothing. Based on the professional judgment of the industrial hygienists performing the survey, each installation was evaluated as to the adequacy of the controls employed. A copy of the article describing the study in more detail is included for the Committee's information (Attachment G).

At OSHA's request, NIOHS published a compendium of all commercially available lasers in 1976. Each laser was classified according to the latest information available from OSHA on the parameters proposed in its draft regulation. Although the OSHA and BRH classes are essentially the same, a few lasers will undoubtedly be assigned different classes because of differences in measurement techniques specified for classification purposes. In general, the BRH measurement technique is more conservative and may result in the assignment of some lasers to a more hazardous classification. This is not surprising or unjustified since BRH is concerned with possible exposure to the general public and not solely occupational exposure. This should not cause any confusion among laser manufacturers or users as long as the difference and the rationale are understood.

Answer 6. Very few documented incidents of eye injury resulting from overexposure to laser radiation have been reported subsequent to the NIOSH occupational health survey of lasers. The laser performance standard promulgated by FDA/BRH should help to minimize the potential hazard by limiting the laser emission to which one could possibly be exposed. Promulgation of an occupational laser standard by OSHA would be useful in creating an awareness of potential laser hazards in the workplace and stimulating the development of occupational laser safety programs.

Answer 7. The two men who developed bilateral contracts worked for the New York Times. A complete radiation survey and medical evaluation was done by NIOSH and a report is currently in press. A copy of the draft report is enclosed and contains the details of the survey (Attachment H). Data from the National Eye Institute indicates that the probability of cataracts for males aged 25–44 years is approximately .00039 (3.9×10^{-4}) for the years 1970–73.

Answer 8. NIOSH has initiated a retrospective epidemiological study of TACAN and radar repairmen. The study is programmed for two years with a total budget of $215,000. The executive summary and the project protocol are enclosed (Attachment I).

According to statistics from the National Cancer Institute for the years 1950–1969, the probability of pancreatic cancer in white males aged 30–34 years is .0000046 or 4.6×10^{-6}. In regard to geographical incidence, no county in Rhode Island has a pancreatic cancer incidence which is statistically different from the U.S. rate. Several counties in southeastern Massachusetts and middle Connecticut do have statistically higher rates. However, NCI has concluded that there is no clearly discernible geographic pattern for the occurrence of pancreatic cancer.

NIOSH has no data on geographical patterns for microwave radiation exposure.

Answer 9. It is regrettable that Mr. Brodeur has implied that NIOSH has been less than responsive in investigating the occurrence of pancreatic cancer in two TACAN repairmen. NIOSH does not have right of entry to Federal facilities. At no time has NIOSH refused or even been reluctant to fully cooperate with the Navy in this matter. At the Navy's request, NIOSH has accompanied their personnel for meetings and surveys of TACAN repair facilities. NIOSH's personnel have virtualy been "on call" to assist the Navy in this investigation.

Answer 10. The list of studies documenting teratogenic effects in pregnant animals exposed to RF radiation is enclosed (Attachment J).

Answer 11. NIOSH currently has two programs addressing industrial hygiene problems associated with coal liquefaction and gasification processes. Both programs are being carried out by our Appalachian Laboratory for Occupational Safety and Health (ALOSH) in Morgantown, West Virginia. Each program requires the identification of radioactive materials released during the process and an evaluation of the potential hazard to the workers. The studies will be completed in fiscal year 1979. Because of the pressing need for guidance in this area, criteria documents are being prepared for coal gasification (scheduled completion fiscal year 1978) and liquefaction (fiscal year 1979) processes. New information from the ALOSH programs will be incorporated into updated criteria documents as soon as possible.

NIOSH has no information on releases of radioactivity to the environment from these processes or from the burning of coal.

Answer. The Radiation Section of NIOSH presently has a staff of five people and the total funding for fiscal year 1978 is approximately $360,000. This section has had considerable impact on the occupational safety and health field since its formation. The group members are well respected in their fields and function very efficiently as reflected in both the quality and quantity of accomplishments. At this time NIOSH feels that resources allocated for radiation research are sufficient to achieve our major goals with our present staff.

The occurrence of radiation sources has increased drastically over the past two decades in all phases of life. The industrial environment is no exception to this trend. In fact, occupational exposure to radiation sources may be accelerating at a faster rate in all types of industrial facilities outside of the nuclear industry than exposure of the general population. Thus, the consideration of radiation hazards has been integrated into the practice of industrial hygiene.

As stated, many Federal agencies presently have radiation research programs and NIOSH has keep abreast of the activities of these agencies. The obvious motive for such interactions is to avoid wasteful duplication of effort but, more important, to apply their research to NIOSH's needs whenever possible. By charter NIOSH must emphasize the protection of the Nation's workforce from all potential occupational hazards including radiation. The nature of the work environment is such that the worker is exposed to many stresses simultaneously, usually at higher levels than is the general public. Consequently, NIOSH's approach to solving the many problems found in the workplace may differ from that employed by other agencies in carrying out their missions.

For example, NIOSH is currently developing a criteria document for the roofing industry. In addition to the solar radiation ((UV, visible and IR) the roofer is exposed to several chemical substances, heat and noise. To provide adequate guidance to the industrial hygienist, all factors must be considered in evaluating and controlling hazardous situations including possible synergisms among the toxic agents. An interdisciplinary approach is mandatory in addressing such problems and expertise must be drawn from many fields to provide solutions.

Another point also deserves attention. With few exceptions other Federal agencies have concentrated their efforts and resources in ionizing radiation programs. NIOSH's Radiation Section has emphasized nonionizing radiation programs. This is obvious from the list of projects previously supplied to the Committee. RF and optical (ultraviolet, visible and infrared) are being given particular attention. Research is presently underway leading to the development of standards for RF and infrared radiation and the updating of ultraviolet radiation criteria document published in 1972.

Because of its overall mandate to occupational safety and health, NIOSH must actively maintain an overall programmatic approach to these issues. Since the Radiation Section provides necessary expertise to other projects and units with NIOSH in addition to its own projects, NIOSH feels that this Section should continue as an organizational entity.

ATTACHMENT B

PHYSICAL HAZARDS

The properties, biological effects, and health hazards associated with physical agents are discussed in this chapter. A physical agent can be defined as an entity without substance (i.e., with minimal matter), yet capable of affecting the biological mechanisms of an exposed worker. The hazards considered are those associated with exposure to the following agents, which will be grouped into three classes for discussion.

RADIATION: ionizing radiation and nonionizing radiation, including ultraviolet, visible, infrared, microwave, radio frequency, and laser.

ATMOSPHERIC VARIATIONS: heat, cold, air pressure.

OSCILLATORY VIBRATIONS: noise, vibration.

Some of these agents are encountered only in specific occupational situations while others may be present in a number of working environments.

RADIATION

Eugene Moss, William Murray, Wordie Parr, Ph.D.
and David Conover, Ph.D.

Radiation is energy which is emitted, transmitted, or absorbed in wave, or energetic particle, form. One can think of the wave as the disturbance that transfers energy progressively from one point to another point in a medium.

The electromagnetic (EM) waves consist of electric and magnetic forces. When these forces are disturbed, EM radiation results. The known EM radiations are grouped into a spectrum according to their frequency and/or wavelength (Table 7). The spectrum consists of a cotinuum of radiation ranging from below radio frequencies to above ionizing; it includes microwave, infrared, visible, and ultraviolet radiation. Although no range of radiation is sharply delineated from another and, in fact, the ranges often overlap, it is convenient to separate these ranges into the above groups because of the physical and biological effects associated with each radiation type.

The range of biological effects of exposure within the EM spectrum is extremely broad and diverse. This is further emphasized by noting the frequency bandwidth covered by the spectrum. Table 7 indicates the band width to encompass at least 10^{7} but, in fact, it extends to a factor of 10^{28} Hz. The amount of energy absorbed by the worker varies considerably over this range. The safety, health, evaluation, and control problems associated with such a range of magnitudes are great. No other area in human research has a similar wide range of the hazards that need to be considered, classified, and regulated.

Table 7. Characteristics and sources of electromagnetic radiation.

Type of radiation	Frequency range (Hz)*	Wave length range**(m)	Energy per photon range (eV)†	Typical industrial sources of exposures	Estimated number of exposed workers
A. IONIZING X-ray γ-ray B-ray γ-particle Proton Neutron	$>3.0\times10^{15}$	$<1.0\times10^{-7}$	$>1.2\times10^{1}$	Electronic tubes, radiography, nuclear power plants, radiation curing, medical uses, uranium mining, sterilization processes.	7×10^{3}
B. NONIONIZING Ultraviolet	7.5×10^{14} to 3.0×10^{15}	1.0×10^{-7} to 4.0×10^{-7}	3.1 to 1.2×10^{1}	Lamps, welding arcs, gas discharge tubes.	86×10^{3}
Visible	4.0×10^{14} to 7.5×10^{14}	4.0 to 7.6×10^{-7}	1.6 to 3.1	Lamps, welding arcs, hot bodies.	96×10^{3}
Infrared	3.0×10^{11} to 4.0×10^{14}	7.6×10^{-7} to 1.0×10^{-3}	1.2×10^{-3} to 1.6	Lamps, welding arcs, hot bodies.	26×10^{3}
Microwaves	3.0×10^{8} to 3.0×10^{11}	1.0×10^{-3} to 1.0	1.2×10^{-6} to 1.2×10^{-3}	Klystron, magnetron.	14×10^{3}
Radio Frequencies	$<3.0\times10^{8}$	>1.0	$<1.2\times10^{-6}$	Plastic sealers, furniture glue.	7×10^{3}

*Hz = Hertz, cycle per second. **m = meter. †eV = electron volts. Note: The given ranges are only approximations.

IONIZING RADIATION

Ionizing radiation has always been a part of man's natural environment, and since the discovery of X-rays and radioactivity, it has become a part of the industrial environment of many workers. The different types of ionizing radiation vary in their penetrative powers as well as in the number of ions they produce in traversing matter. The latter is important in that biological effects vary with ion density (the number of ions produced per unit length of track).

Ionizing radiations are produced naturally by the decay of radioactive elements or artificially by such devices as X-ray machines and high energy accelerators. A radioactive nucleus is one that spontaneously changes to a lower energy state, emitting particles and often gamma rays in the process. The particles commonly emitted are alpha particles and beta particles. High energy accelerators can produce all of the above particles plus protons, neutrons, and X-rays. The following sections describe some of the more commonly encountered types of ionizing radiation.

Alpha particles, which interact readily with matter to produce ions, usually have energies of from 4 to 8 million electron volts (Mev). They travel a few centimeters in air and up to 60 microns into tissue. The high energy and short path result in a dense tract of ionization along the path of the particles, which produces serious biologic damage in the tissues with which the particles interact. Alpha particles will not penetrate the stratum corneum of the skin and thus are not an external hazard; but if alpha-emitting elements are taken into the body by inhalation or ingestion, serious internal exposure problems may result.

Beta particles interact much less readily with matter than do alpha particles and will travel up to a few centimeters into tissue or many meters in air. Exposure to external sources of beta particles is potentially hazardous, but exposure internally is more hazardous.

Protons with energies of a few Mev are produced by high-energy accelerators and are quite effective in producing tissue ionization. The path length of a proton is somewhat longer than the path of an alpha particle of equivalent energy.

Gamma rays and X-rays are electromagnetic radiations with similar properties. X-rays, in general, have longer wave lengths, lower frequencies, and, therefore, lower energies than gamma rays. Gamma rays are produced by nuclear processes, while X-rays may result from the electronic structure of the atoms or from the slowing down of high-speed electrons. X-rays and gamma rays are primarily an external hazard and their biologic effects are better known than those of any of the other ionizing radiations. Examples of gamma emitters used in industry are cobalt-60, cesium-137, and iridium-192. X-rays may also be encountered during the manufacture and use of electronic tubes and electron microscopes.

Neutrons have about the same mass as protons, but react much differently since they are electrically neutral. These uncharged nuclear particles upon collision with matter may cause the release of all the above types of ionizing radiation. Neutrons can be produced up to several Mev by reactors, accelerators, or certain beryllium-enriched sources.

ROUTES OF ENTRY

The conditions presented by external radiation sources are entirely different from those presented by internal radiation sources which have been deposited in the body, with their attendant continuous irradiation of cells and tissue.

Entry of radiation sources into the body during occupational exposures is principally from breathing air containing particulate or gaseous radionuclides, although ingestion and skin absorption can be important.

Implantation under the skin may occur as the result of accidental skin puncture or laceration. Once inside the body, radionuclides are absorbed, metabolized, and distributed throughout the tissues and organs according to the chemical properties of the elements and compounds in which they exist. Their effects on organs or tissues depend on the type and energy of the radiation and residence time.

The effect from external radiation sources depends on the penetrating ability of the particular radiation. Thus, alpha radiation is of no concern externally, and beta is stopped in the outer tissues, the depth depending on energy. Very low energy X- or gamma radiation is attenuated quite rapidly.

HARMFUL EFFECTS

The early experience of radiation workers (including various nuclear accidents, exposure of radium dial-painters, casualties from atomic bomb explosions) and data from research projects provide clear evidence that high levels of ionizing radiation definitely create somatic damage and may induce genetic damage. The occupational somatic effects include radiodermatitis, epilation, acute radiation syndrome, cancer, leukemia, cataracts, sterility, and life span shortening. The genetic effects resulting from occupational exposures are to a great extent still unknown. Moreover, it is important to remember that a mutation produced by radiation is similar to one effected by a mutagenic chemical or to one occurring spontaneously.

In general, the sequence of events following radiation exposure may be classified into three major periods. The first period is the latent period, defined as the time lapse between the initial radiation event and the first detectable effect. Since the latent period can range from days to years, it is often divided into short-term (days or weeks) and long-term (months or years) effects. The second period, the period of demonstrable effects, occurs immediately after the latent period and is that time period when certain discrete biological effects can be observed. The final period is the recovery period.

The effects from occupational exposure to ionizing radiation are usually localized, leading to erythema or radiodermatitis. An acute radiation syndrome (ARS) episode occurs very rarely. An episode of this type involves whole body exposure exceeding 100 roentgens given in a very short time.

Initial symptoms of ARS are nausea, vomiting, diarrhea, weakness, and shock. Following a latent period of 2 to 14 days, symptoms of fever and malaise occur. During this same period of time, hemorrhagic lesions of the skin often appear, and by the third week, epilation occurs. Painful ulceration, both internal and external, may appear over the whole body and bloody diarrhea may occur. Death may result from severe bone marrow depression if the radiation exposure level is high. The patient is also susceptible to infection of many types.

Among the long term effects are an increased incidence of carcinoma, as noted in the radium dial painters and uranium miners; the embryological effects, as noted in pregnant working women; the cataractogenic effects, as seen in certain radiologists and nuclear physicists; and shortening of the life span.

Overexposure of a worker to either an external or internal source of radiation creates a medical emergency. In serious situations involving a release of radioactive material, the degree of contamination must be determined before the individual can be admitted to a hospital. A much more detailed discussion of the medical aspects of radiation accidents is available in the volume by Saenger (1963) listed in the bibliography that follows.

POTENTIAL OCCUPATIONAL EXPOSURES

With the widespread use of radioactive isotopes in industry and the increasing use of X-ray sources, ionizing radiation exposures may occur in a wide variety of occupations. The following examples show the diversity of occupations potentially exposed to ionizing radiation.

Aircraft workers
Atomic energy plant workers
Biologists
Cathode ray tube makers
Ceramic workers
Chemists
Dental Assistants
Dentists
Dermatologists
Drug makers
Drug sterilizers
Electron miscoscope makers
Electron microscopists
Electrostatic eliminator operators
Embalmers
Fire alarm makers
Food preservers
Food sterilizers
Gas mantle makers
High voltage television repairmen
High voltage vacuum tube makers
High voltage vacuum tube users

Industrial fluoroscope operators
Industrial radiographers
Inspectors using, and workers in
  proximity to, sealed gamma ray
  sources (cesium-137, cobalt-60,
  and iridium-192)
Klystron tube operators
Liquid level gage operators
Luminous dial painters
Machinists, fabricated metal product
Military personnel
Nurses
Oil well loggers
Ore assayers
Pathologists
Petroleum refinery workers
Physicians
Physicists
Pipeline oil flow testers
Pipeline weld radiographers
Plasma torch operators
Plastic technicians
Prospectors
Radar tube makers
Radiologists
Radium laboratory workers
Radium refinery workers
Research workers
Television tube makers
Thickness gage operators
Thorium-aluminum alloy workers
Thorium-magnesium alloy workers
Thorium ore producers
Tile glazers
Uranium dye workers
Uranium mill workers
Uranium miners
Veterinarians
X-ray aides
X-ray diffraction apparatus operators
X-ray technicians
X-ray tube makers

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ULTRAVIOLET RADIATION

Ultraviolet (UV) radiation is an invisible radiant energy produced naturally by the sun and artificially by arcs operating at high temperatures. Artificial sources commonly found in industry are germicidal and black-light lamps, carbon arcs, welding and cutting torches, electric arc furnaces, and laboratory equipment.

Since the eyes and skin readily absorb UV radiation, they are particularly vulnerable to injury. The severity of radiation injury depends on factors which include exposure time, intensity of the radiation source, distance from the source, wavelength, sensitivity of the individual, and presence of sensitizing agents.

HARMFUL EFFECTS

Sunburn (erythema) is a common example of the effect of UV radiation on the skin. Repeated UV exposure of lightly pigmented individuals may result in actinic skin — a dry, brown, inelastic, wrinkled skin. There are telangiectases on the forehead, and neck movements produce lines on the nape in an angular pattern. Actinic skin is not harmful in itself, but it is a warning that conditions such as senile keratosis, squamous cell epithelioma, and basal cell epithelioma may develop.

Since UV radiation is not visible, the worker may not be aware of the danger at the time of exposure. Absorption of the radiation by the mucous membranes of the eye and eyelids can cause conjunctivitis (commonly known as "ground glass eyeball" or "welder's flash"). Lesions may also be formed on the cornea at high exposure levels (photokeratitis). Such injuries usually manifest themselves 6 to 12 hours after exposure. The injuries may be very painful and incapacitating, but impairment is usually temporary.

Photosensitizing agents have action spectra which are frequently in the ultraviolet range (Table 8). Some drugs and many plants, including figs, limes, parsnips, and pink-rot celery, carry photosensitizing chemicals believed to be furocoumarins and psoralens. Symptoms upon contact are those of an exaggerated sunburn with blisters frequently present. The most important industrial photosensitizer is coal tar which has an action spectrum in the visible range.

Ultraviolet light can also act in a nonspecific manner in the production of herpes simplex and chronic discoid lupus erythematosus.

PERSONAL PROTECTIVE METHODS

Protective measures are essential for workers exposed to high-intensity UV sources. Goggles, face shields, and masks provide protection for the eyes; protective clothing and barrier creams minimize skin exposure. Shiny metal surfaces reflect UV radiation and, when possible, should be removed from the work area. Reflections from lamp housings, walls, ceilings, and other surfaces should be reduced by coating these surfaces with a pigmented paint of low UV reflectance. Operations that produce high levels of UV should be placed behind enclosures to absorb the radiation and shield nearby workers from exposure.

POTENTIAL OCCUPATIONAL EXPOSURES

UV radiation exposure is generally present wherever occupations involve sunlamps, the outdoor sun, welding arcs, plasma torches, lasers, laboratory research, printing processes, drying and curing processes, nondestructive testing, environmental test chambers, medical devices and materials, and chemical processing and manufacturing. Occupations associated with potential UV radiation exposure include the following:

Agricultural workers
Bacteriologists
Bath attendants
Beauty salon workers
Brick masons
Cattlemen
Chemists
Construction workers
Dentists
Farmers
Fishermen
Food irradiators
Gardeners
Graphic illustrators
Greenskeepers
Horticultural workers
Laboratory workers
Lamp testers
Landscapers
Lifeguards
Lithographers
Lumberjacks
Maintenance workers
Meat curers
Metal casting inspectors
Microscopist
Military personnel
Movie projectionists
Nurses
Oilfield workers
Open pit-miners
Opticians
Optometrists
Outdoor maintenance workers
Paint and color testers
Paint curers
Physicians
Physicists
Physiological optics workers
Photo-bacteriologists
Phototherapy technicians
Pipeline workers

Table 8. Some examples of action spectra of normal and abnormal reactions in man.*

Condition	Wavelength Range (nm)	Maximum Reaction (nm)
Normal sunburn	290-320	297-307
Artificial light sources	250-320	250
Melanin pigmentation	290-320 320-480	290-310
Vitamin D production	290-310	290
Hyperbilirubinemia of prematurity	Blue visible spectrum	440-470
UV carcinogenesis	290-320	290-310
Solar urticaria	290-320 320-400 400-600	varying
Porphyria photosensitivity	380-600	400-410
Xeroderma pigmentosum	290-340	293-307
Polymorphic photodermatitis	290-320 320-400	290-320
Lupus erythematosus (LE) and discoid LE	290-320	
Solar (actinic) degeneration	290-400	?
Photoallergic reactions to halogenated salicylanilides and other related compounds	320-380	330-360
Phototoxic reactions to drugs	320-400 290-320	320-400
Psoralens (8-methoxy- and trimethylpsoralen)	320-380	330-360

*Used with permission from Sunlight and Man. T. B. Fitzpatrick et al., eds. Table 4. University of Tokyo Press, Tokyo, Japan.

Plasma torch operators
Plastic curers
Policemen (including crossing guards)
Postmen
Printers
Production workers in chemical
  processing
Railroad track workers
Road workers
Seamen
Ski instructors
Space simulator workers
Sportsmen
Surveyors
Textile inspectors
Tissue culture workers
Tobacco irradiators
Vitamin D synthesis workers
Welders
Welder foremen
Wood curers

VISIBLE RADIATION

Visible radiation, or light, from either the sun or artificial sources, is probably one of the more important occupational health considerations because of its major role in our daily life. Only within the last few years have investigators begun to discover various subtle physiological and biochemical responses to light.

Several human systems respond directly or indirectly to visible radiation. A direct effect has been defined as a chemical change in the composition of a tissue resulting from the absorption of light energy within the tissue. Because few direct effects of light have been documented, light is not considered a major occupational health hazard.

Indirect effects of light, however, can occur — not from absorption of light energy in tissues — but from the action of chemical signals liberated by cells in the body. Examples of this relationship of light to biological rhythms, include physical activity, sleep, food consumption, etc. Another well-known indirect effect is the inhibition of melatonin synthesis by the pineal gland which in turn affects maturation and activity of the sex gland. The various known classifications of abnormal biological reactions to light are shown in Table 9.

HARMFUL EFFECTS

One of the controversial issues associated with visible radiation is the effect of illumination on job performance. The concept exists that the levels of illumination and source luminance routinely encountered in interior working environments may constitute some type of an ocular health hazard. Studies on humans gazing at the sun and on rats and mice under common interior lighting intensities have produced evidence to indicate a hazard; these studies, however, have not been considered conclusive and the results have been disputed.

At the 1974 NIOSH symposium on illumination, several conclusions were agreed upon:

1) High levels of lighting can cause damage to the eye, i.e., retinal or macular degeneration
2) Poor lighting conditions can cause aesthenopia

3) With the possible exception of miner's nystagmus, such organic diseases as glaucoma, cataracts, and retinal degeneration do not result from exposure to low levels of illumination.

The consensus seemed to be that if there is sufficient illumination to perform a task reasonably well, then there is sufficient light to meet the safety criteria.

Although the etiology of asthenopia (eye strain) is debatable, it appears that repeated occurrences probably do not lead to any permanent eye damage. Workers over 40 years of age will probably encounter more symptoms of asthenopia (headache, tired eyes, irritation) since they require more light to perform a similar job than younger workers.

POTENTIAL OCCUPATIONAL EXPOSURES

Virtually all occupations offer exposure to the potential hazards of defective illumination. Some occupations, however, require unusually close, fine work and attention to detail for many hours a day. Some of these occupations are:

Draftsmen
Electronic equipment assemblers
Engravers
Jewelers
Quality control inspectors
Watchmakers

INFRARED RADIATION

All objects having temperatures above absolute zero emit infrared radiation (IR) as a function of temperature. In biological systems the major insult of IR occurs as a result of a rise in temperature of the absorbing tissue.

The physical factors associated with temperature rise are the wavelength, heat conduction parameters, exposure time, and total amount of energy delivered to the exposed tissue. Since IR photons are low in energy, they probably do not enter into photochemical reactions with biological systems. Molecular interaction with radiation in the IR regions are characterized by various vibrational-rotational transitions resulting in an increase in thermal energy of the molecule.

HARMFUL EFFECTS

Since the primary effect of IR on biological tissues is thermal, the skin provides its own warning mechanism by having a pain threshold below that of the burn threshold.

In the eye, however, there is no adequate warning mechanism to protect against lenticular damage. Cataracts may be produced by prolonged exposure to wavelengths at energy levels that do not normally burn the skin. The classic ocular effect observed after many years of IR exposure is a posterior cataract, sometimes called glassblower's or furnaceman's cataract. This type of cataract has a lengthy latent period (10 to 15 years) in individuals chronically exposed to IR which has made it difficult to determine threshold values.

The present etiology of IR-induced cataracts is thought to be directly correlated with the amount of energy initially absorbed by the iris and then transferred to the lens. The threat of cataract formation is primarily from wavelengths below 1400 nanometers. Longer wavelengths may produce corneal damage, the difference being due to the site of energy absorption.

The primary biological effect of IR on the retina and choroid is thermal in nature, with the amount of damage being proportionate to the length of exposure. If the radiation intensity is low enough, however, the normal retinal blood flow may be sufficient to dissipate any heat generated. Nevertheless, due to the focusing effect of the anterior ocular components, small amounts of IR radiation can produce a relatively intense point energy distribution on the retina resulting in a lesion. The effects of IR on the lid and cornea can be considered as ordinary cutaneous burns.

POTENTIAL OCCUPATIONAL EXPOSURES

A wide range of IR wavelengths representing large variations in temperature is encountered in many industries from direct (lamps) and indirect (heat) sources. Occupations potentially associated with infrared radiation exposures include the following:

Bakers
Blacksmiths
Braziers
Chemists
Cloth inspectors
Cooks
Dryers, lacquer
Electricians
Firemen, stationary
Foundry workers
Furnace workers
Gas mantle hardeners
Glass blowers
Glass furnace workers
Heat treaters
Iron workers
Kiln operators
Laser operators
Motion picture machine operators
Plasma torch operators
Skimmers, glass
Solderers
Steel mill workers
Stokers
Welders

MICROWAVE/RADIOFREQUENCY RADIATION

Various estimates have been made of the number of workers potentially exposed to microwave/radio frequency (RF) radiation sources in industry, including one estimate of approximately 21 million workers at risk (See Reference 110). Obviously, not every worker in every job is exposed to hazardous microwave/RF radiation levels, but an exposure of even 25 percent of the workers potentially at risk would still present a significant target population. Because of the size of this potentially exposed group at work, the continuing expansion of microwave use in industry, and the lack of widely known bioeffects data, a list of references is offered in citations to the material presented. Also the following

Table 9. Classification of abnormal reactions to light in man.*

Type	Light Alone	Light + Exogenous Agent	Light + Metabolite	Light + Abnormal Skin or Disease
Genetic	Ephelides (freckles)		Porphyrias: Erythropoietic porphyria Erythropoietic protoporphyria Variegate porphyria (mixed porphyria) Hereditary coproporphyria	Xeroderma pigmentosum Hartnup syndrome Oculocutaneous albinism Cockayne's syndrome Rothmund-Thomson syndrome Hailey-Hailey disease Vitiligo Darier-White disease Bloom's syndrome Phenylketonuria(?)
Chemical, phototoxic		Topical and oral drugs Phytophotodermatitis		
Chemical, photoallergic		Topical and oral drugs		
Chemical induction of disease		Lupus erythematosus from sulfonamides, hydralazine, reserpine, griseofulvin, oral contraceptives, etc.	Porphyria from hexachlorobenzene, estrogens, griseofulvin, stilbesterol, alcohol	
Nutritional				Kwashiorkor; Pellagra
Infectious				Lymphogranuloma venereum Herpes simplex

Table 9. Classification of abnormal reactions to light in man.* (Continued)

Type	Light Alone	Light + Exogenous Agent	Light + Metabolite	Light + Abnormal Skin or Disease
Degenerative and neoplastic	Chronic solar skin damage Solar keratoses Basal cell carcinoma Squamous cell carcinoma Malignant melanoma(?) Connective tissue degeneration (wrinkling) Telangiectasia			
Miscellaneous	Acute solar skin damage (sunburn) Hydroa aestivale and hydroa vacciniforme Disseminated superficial actinic porokeratosis	Phytophotodermatitis	Porphyria cutanea tarda	Lupus erythematosus (cutaneous and systemic) Solar urticaria Polymorphous light eruption Malignant carcinoid Pemphigus foliaceus Dermatomyositis

*Used with permission from Sunlight and Man. T. B. Fitzpatrick et al., eds. Table 1. University of Tokyo Press, Tokyo, Japan.

units of measurement are defined: μWcm^{-2} = microwatts per centimeter squared; MHz = 10^6 Hz; GH = 10^9 Hz; V•m^{-1} = volts per meter; and A•m^{-1} = amperes per meter.

HARMFUL EFFECTS

Effects from exposure to microwave/RF radiation due to heating have been well documented, but evidence for those occurring in the absence of a tissue temperature rise is incomplete and in dispute (1-3).

Frey (4) reported an acoustic response which he postulated to be a direct auditory nerve response to microwaves. The phenomenon occurred instantaneously in human subjects exposed to power densities as low as 100 μW•cm^{-2}. This specific effect was perceived as a buzz, ticking, or knocking, depending upon the pulse width and pulse repetition rate. The greatest sensitivity was observed in humans within the frequency range 300 MHz to 1200 MHz. The area directly over the temporal lobe of the brain was identified as the most sensitive area.

More recently Lebovitz (5) proposed that the cochlear hair cell structures within the vestibulo-cochlear complex of the human ear could directly respond to stimulation from pulse modulated microwave radiation. Guy (6) confirmed the reports of human auditory perception of pulse modulated microwave radiation and demonstrated a similar auditory response in cats which disappeared when the fluid was removed from the vestibulo-cochlear complex. Sommer and Von Gierke (7) confirmed the existence of this specific effect but stated that the effect was due to electromechanical transduction rather than direct stimulation of neural fibers or cortical neural tissue.

The possibility that microwave radiation could interact with the central nervous system (CNS) without detectable heating has been suggested by several investigators (8-18). Osipov (12) feels that some of the effects which have not been attributed to heating may in fact be due to microthermal heating. Microthermal heating is very localized and the temperature rise could not be detected by conventional temperature measurement techniques. Contrary to the subjective clinical complaints reported previously, recent studies [Baranski (8)] have used more objective measurements, better controls, improved statistics, a clearer description of the experimental design, and well documented experimental procedures.

In the Soviet and Eastern European literature (19-32), the following symptoms were reported as associated with 10/20-year exposure to microwave/RF radiation: headache, increased suspectibility to fatigue, diminished intellectual capabilities, dullness, partial loss of memory, decreased sexual ability, irritability, sleepiness and insomnia, and emotional instability. Objective disorders include sweating, hypotension, dyspnea, pains in the chest, sinus arrhythmias, bradycardia, and other cardiovascular problems. Electroencephalogram (EEG) recordings and the associated response times have been shown to be altered by microwave/RF exposure. Responses are characterized by initial excitation followed by inhibition. Also noted were threshold shifts generally in the direction of increasing thresholds for sensory perception, increases in the latent period of the condition-reflex reaction, and disruption of vegetative system regulatory and compensatory functions.

Other changes that have been observed are: in the histamine level in the blood (33-36), decreased cholinesterase levels in persons and animals exposed to microwave/RF radiation (37-43); alterations in the protein fractions, ions, histamine content, hormone and enzyme levels, and immunity factors (27,33-37,44-52); leukocytosis (monocytosis, lymphocytosis, and eosinophilia); recticulocytosis; and thrombocytopenia.

Of particular significance are studies of genetic and reproductive system effects because of the possible impact in large populations over long periods of time. One study suggested a possible correlation between paternal radar exposure and mongoloidism of the progeny (53). Several occupational studies have suggested possible disturbances in human reproductive system functions (27,33,54). Animal studies with low intensity exposures report reproductive system disturbances and cases of detrimental effects on the progeny (55-59).

Changes in menstrual patterns, retarded fetal development, congenital effects in newborn babies, decreased lactation in nursing mothers, and an increased incidence of miscarriages for women working with microwaves have been reported [Marha et al. (60,61]. As a result, Czechoslovakian employment practices (60) prohibit women of reproductive capacity from working with RF radiation sources. Teratogenic effects on the fetus of a mother treated with RF radiation at the beginning of pregnancy (62) and impaired embryogenesis in humans and animals, particularly when RF irradiation occurred during the initial stages of pregnancy (63) have been reported. Rubin (64) reported on a case of microwave exposure of the human female pelvis during early pregnancy and prior to conception. The patient was irradiated during the first 59 days of pregnancy and aborted on day 67. The author warned against treating pregnant women with microwave radiation unless a careful menstrual history is taken (64).

Microwave/RF teratogenic effects have been produced in mealworm beetle pupae (65, 66), chick embryos (67,68), rats (69), and mice (70). The teratogenic effects noted in rats (69) were produced following irradiation at the same frequency (27.12 MHz) where the majority of RF power sources operate. A single acute RF exposure for ten minutes at 27.12 MHz between the first and the 16th day of pregnancy was sufficient to produce teratogenic effects in rats (69). The head, palate, limbs, tail, and abdomen were malformed following RF irradiation.

Primigravid mice irradiated at 2450 MHz with an accompanying injection of cortisone on days 11, 12, 13, and 14 of gestation gave birth to greater numbers of stillborn and deformed fetuses (71). Microwave irradiation of white CF1 mice at 2450 MHz with a mean absorbed dose rate of 107 mW/gm for four minutes produced teratogenic effects on gestation days 3, 4, 8, 10, and 12 (72).

One of the more important bioeffects related to temperature rises induced by microwave radiation in biological media is cataract formation (73-81). Kramer et al. (82) concluded that a temperature of at least

41°C within the rabbit eye behind the lens is needed for cataractogenesis.

Weiter et al. (83) reported that the ascorbic acid content of rabbit lenses is a good index of microwave induced cataracts. The ascorbic acid content of rabbit lenses decreased with increasing microwave irradiation.

Behavioral effects observed after exposure to microwave RF radiation indicate that the modifications of normal behavior are related to the increased body thermal burden. Thomas et al. (84) observed that a rat's ability to perceive a constant time interval was degraded by irradiation for times sufficient to cause whole body heating. Hunt et al. (85) found that irradiation of rats at 2.45 GHz caused a decrease in their ability to swim a water alley and that errors of omission in performing visual discrimination tests increased immediately following microwave irradiation. Soviet investigators, however, have concluded that behavioral effects are not primary related to whole body heating (86).

A summary of available information on biologic effects and health hazards was presented in 1974 at an international symposium held in Warsaw, Poland (87).

Radio Frequencies Below 300 MHz

Previously, it was thought that there were no biological effects for frequencies below 300 MHz (0.3 GHz). Beginning in 1977, the United States Information Agency (USIA), and the United States Air Force (USAF) funded bioeffects research within the radiofrequency (RF) band which extends from 10 to 300 MHz in order to evaluate the accuracy of the 1977 standards for this frequency band. Both the ANSI C95.1 and the OSHA regulations (88) specify a frequency range from 10 MHz to 100 GHz.

Kall (89,90) studied the effects on rats exposed to RF (6 and 21 MHz) fields, similar to those found in the industrial environment. He noted that the gastrointestinal motor activity increased and cholinesterase activity decreased significantly. From the results of these studies on rats, Kall (90) recommended to the USIA that exposure standards should be modified to specify an electric field strength of 1500 $V \cdot m^{-1}$ and a magnetic field strength of 5 $A \cdot m^{-1}$ for the frequency range from 3 to 30 MHz.

The theoretical data of Lin (91) for a spherical phantom model simulating man has shown that the *magnetic field component* of the RF(1-20MHz) field may be the *most hazardous*. For RF fields close to typical RF power sources, the heating of the theoretical human phantom model due to the magnetic field component can be even larger. These conditions should be carefully considered when attempting to estimate the potential hazard from an RF radiation field.

Bawin (92,93) demonstrated EEG changes in cats and increases in calcium efflux in chicks following exposure to amplitude modulated 147 MHz fields. The amplitude modulation frequency (8-16 MHz) approached that of physiological bioelectric function rhythms. Further examples of alterations in circadian rhythms by RF exposure are effects on the cell division rate of corneal epithelium (94,95) and changes in rate of bone marrow cell mitoses (96).

Prince et al. (97) demonstrated that RF fields (10-27 MHz) can produce a marked increase in lymphocyte mitotic activity 71 hours post-exposure in monkeys. Lovely et al. (98) reported no in vitro lymphocyte mitotic activity 48 hours following RF exposure of monkeys.

Stavinoha et al (99) reported that near-field exposures of mice to 19 MHz caused definitive changes in lymphocytes and other white blood cells. The number of polymorphonuclear leukocytes was significantly higher and the number of lymphocytes was significantly lower in the irradiated group as compared with that of the control group. These alterations in white blood cells could not be duplicated in animals exposed in a hot air oven which elevated the colonic temperature the same amount as the RF field exposures. Czerski (95) showed alterations in the diurnal rhythm of peripheral white blood cells and granulocyte precursor mitoses in Guinea pig bone marrow. The results suggest a cumulative effect on the lymphatic system associated with decreased antibody production. This would imply that employees exposed to RF radiation might be more susceptible to infection and more susceptible to allergies encountered in the work environment.

The immunosuppressive and anti-lymphocytic actions of the adrenal glucocorticoids are well known. It is possible that immunologic effects caused by microwave RF fields are related to glucocorticoid levels. Guillet et al (100) reported the concentration of adrenal glucocorticoids in the blood increased following microwave irradiation.

Bollinger et al. (101) demonstrated that the uptake of H-3 Thymidine by lymphocytes isolated from mice exposed to RF fields ranged from 2.5 to 5 times that of control animals. Frazer (102) reported that the proportion of rat lymphocytes fell to 48.5% following RF irradiation. The total segmenters increased from 27.8 to 46.8%. It is not known whether these results indicate a direct effect on the cell population or an indirect thermal interaction followed by a rapid endocrine response. Froehlich (103) has shown that these effects could occur at the molecular level by either mechanism. Cody et al. (104) demonstrated alterations in the molecular spectra of biologically significant compounds, such as RNA, when exposed to RF radiation.

It is important to consider data which show that the distribution and magnitude of the absorbed power, *hence the expected biological effects*, varied greatly with exposure conditions. Bussey (104) found that the field intensity and distribution are markedly different in rats and primates. Guy et al. (106) measured field distributions in realistic models of man. The distribution of absorbed power in models of man was highly non-uniform with maximum power absorption (and associated localized temperature rises) occurring in the following locations: axilla, gonads, perineum, lateral thorax, ankles, sternum, forearms, tibia and fiibula, knees, neck, clavicle, shoulders and back. Persons industrially exposed to RF have complained of sensations of warming in many of the above mentioned locations.

Research (107-108) has indicated that the maximum amount of microwave/RF radiation is absorbed within the RF frequency range of approximately 25-26 MHz. Thus, consideration of the results of hyperthermia in the anatomical locations specified by Guy (106) should be of great interest.

For microwave/RF bioeffects dependent on power absorption, human RF exposures from approximately 25-26 MHz represent the greatest potential hazard. Industrial RF exposure measurements performed by NIOSH (109,110) show that the vast majority of industrial RF sources operate from 10-40 MHz and that more than 70% of the sources surveyed exceeded applicable personnel RF exposure standards.

POTENTIAL OCCUPATIONAL EXPOSURES

The following is a list of occupations with specific activities and/or products in which microwave/RF radiation is present and may be a potential hazard.

- Automotive workers
    - Drying of trim base panels
    - Embossing of heel pads to carpets
    - Heat-sealing body interior trim panels
    - Heat-sealing upholstery covers for seats and backs
    - Heat-sealing convertible tops
- Food products workers
    - Finish-drying of "polishing" baked goods
    - Inhibiting enzyme action
    - Melting chocolate prior to tempering
    - Thawing frozen baked goods
- Furniture and wood workers
    - Decking assembly
    - Door lamination
    - Fiberboard fabrication
    - Laminated beams
    - Lumber edge gluing
    - Plywood panel patching
    - Plywood or particleboard scarf gluing
    - Posts
    - Rafters
    - Ski lamination
    - Veneer panel gluing
- Glass fiber workers
    - Drying glass fibers on forming tubes
    - Drying roving packages
    - Drying and curing sizing on machine packages
    - Drying coatings on continuously moving strands
- Paper product workers
    - Correcting moisture profile on continuously moving webs
    - Drying twisted twine packages
    - Drying resin coatings

- Plastic heating sealing workers (cont.)
  - Gluing paper
  - Heating coating on continuous webs
- Plastic heat-sealing workers
  - Acetate box covers
  - Advertising novelties
  - Appliance covers
  - Aprons
  - Baby Pants
  - Beach Balls
  - Belts and suspenders
  - Blister packages
  - Book covers
  - Capes
  - Check book covers
  - Charge cards
  - Convertible tops
  - Cushions
  - Diaper bags
  - Display boxes
  - Electric blankets
  - Food packages
  - Fountain pens
  - Garment bags
  - Gas masks
  - Goggles (industrial)
  - Hand bags
  - Hat covers
  - Index cards
  - Lampshades
  - Liquid containers
  - Luggage
  - Machine covers
  - Mattress covers
  - Milk cartons
  - Oxygen tents
  - Packages
  - Pharmaceuticals
  - Pillow cases
  - Pillow packages
  - Plastic gloves
  - Pool liners
  - Protective clothing
  - Rain apparel
  - Racquet bags
  - Refrigerator bags
  - Shoes
  - Shoe bags
  - Shower curtains

  - Slip covers
  - Splatter mats
  - Sponge backings
  - Sport equipment
  - Tobacco pouches
  - Toys
  - Travel cases
  - Umbrellas
  - Wallets
  - Waterproof containers
  - Wire terminal covers
- RF/microwave application workers
  - Advertising — RF excited gas display signs
  - Ceramics — dry ceramic bodies
  - Chemical — chemical activation
  - Electronics — tube aging and testing
  - Laser — RF excited gas lasers
  - Medical-diathermy
  - Scientific equipment — low temperature ashing of samples
  - Tobacco — dry blended tobacco and dry cigars
  - Welding — RF stabilized welders
- Rubber products workers
  - Drying latex foams
  - Gelling latex foams
  - Preheating prior to molding
  - Preheating prior to curing latex foams
- Textile workers
  - Drying rayon cake packages
  - Drying wound packages
  - Drying impregnated or coated yarns
  - Drying slasher coatings
  - Drying continuous webs

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LASER

The word laser is an acronym for "light amplification by stimulated emission of radiation." Lasers operate in the infrared and ultraviolet as well as visible regions. The name is descriptive of the physical principle involved in the production of the radiation. By stimulating or forcing atoms to emit photons, the resultant laser beam is coherent. This means that the photons in the beam are monochromatic and are in phase with each other. Since the laser beam is highly coherent it diverges slowly, maintains its divergency over a long distance, and has a high radiant exposure. As a result of these properties, laser light differs considerably from visible light.

At one time shortly after the development of the first working model in 1960, the laser was referred to as a solution looking for a problem. This situation has changed. By 1975 the development and marketing of new laser devices had resulted in the availability of almost 2500 models from 175 manufacturers and distributors. The most common lasers are shown in Table 10.

HARMFUL EFFECTS

The laser by virtue of its design is able to concentrate a large amount of energy in a small cross-sectional area. Consequently, individuals working with such devices encounter a potential hazard. The critical organs are the eye and skin and the resulting biological effects are similar to those produced by conventional optical radiation sources. Since energy must be absorbed to produce an effect, the degree of injury depends upon the wavelength of the laser and the capacity of the tissue to absorb energy of that particular wavelength.

The primary hazard from laser exposure is ocular damage. Overexposure of skin varies from a mild erythema to blisters and charring. Chronic or repeated exposures to laser radiation may have a long-term effect, but this is normally discounted.

Infrared radiation (700-1400 nm) has also been implicated as a cataractogenic agent. Overexposure to UV laser radiation can result in keratoconjunctivitis. Cataracts can be induced by UV lasers operating in the 300-400 nm range. Infrared lasers (1400 nm to 1 mm present a corneal hazard only.

PERSONAL PROTECTIVE METHODS

If the radiation levels are kept below those injurious to the eye, other tissues will not be harmed. The thresholds for skin and ocular damage are the same for both UV radiation and for IR (1400 nm – 1mm ranges. It is assumed that both organs are equally sensitive. The visible and near IR wavelengths (400-1400 nm) are readily transmitted through the ocular media to the retina. Not only is this radiation transmitted, it is focused by the lens onto the fovea centralis which concentrates the energy onto a very small spot.

Thus, in this spectral region, the eye (retina) is far more sensitive

Table 10. Common laser devices and applications.

Type	Wavelength(s)	Applications
Argon (Ar)	458-515 nm	alignment surveying instrumentation halography photocoagulation
Carbon dioxide (CO_2)	10.6 μm	material processing optical radar instrumentation surgery techniques
Dye	variable	instrumentation
Gallium arsenide (GaAs)	850-950 nm	instrumentation ranging intrusion detection communications
Helium cadmium (HeCd)	325, 442 nm	alignment surveying
Helium neon (HeNe)	632.8 nm	alignment surveying halography ranging intrusion detection communications
Neodymium glass (Nd glass) Neodymium YAG (Nd YAG)	106 μm	material processing instrumentation optical radar surgery
Ruby	694.3 nm	material processing holography photocoagulation ranging

than the skin by several orders of magnitude, and even a diffuse reflection from a high power laser can present an ocular hazard. An action spectrum has been recently developed to account for the variation in retinal sensitivity with wavelength for exposure times greater than 10 seconds. The minimum threshold dose for retinal lesions occurs at 440 nm and is thought to be due to a photochemical process rather than to a thermal mechanism as in wavelengths greater than 500 nm.

POTENTIAL OCCUPATIONAL EXPOSURES

Lasers are used in many diverse situations such as drilling holes in metals and baby bottle nipples, cutting diamonds, aligning wings on airplanes, repairing detached retinas, and taking three-dimensional pictures.

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NIOSH ATTACHMENT C

ESTIMATED NUMBER OF U.S. WORKERS POTENTIALLY EXPOSED TO ELECTROMAGNETIC RADIATION

(By C. E. Moss, D. L. Conover, W. E. Murray, and A. Kohre*)

I. INTRODUCTION

Radiation is characterized as energy which is emitted, transmitted, or absorbed in wave or particulate form. Certain waves consist of electric and magnatic forces which when disturbed in some manner produce electro-magnetic (EM) radiation. The known EM radiations are grouped into a spectrum arranged by frequency and/or wavelength. The spectrum includes the radio frequency, microwave, infrared, visible, ultraviolet, gamma and x-ray regions. These regions of the spectrum are not sharply delineated from each other and, in fact, the regions often overlap. It is convenient to separate these regions as shown in Table 1 due to the nature of the physical and biological effects that are produced.

It is with the biological effects that the real need to comprehend the importance of the EM spectrum becomes apparent. Table 2 lists some of the reported biological hazards, ranked by a severity scale, that have been associated with the spectrum. One sees that the range of harmful biological insults produced by the EM radiations are very broad and diverse. While something is known about the various occupational hazards from EM exposures, very little information exists concerning (a) the number of workers by occupations exposed to EM radiation, and (b) the types of EM radiation sources that expose workers. Such information is essential if any meaningful occupational EM radiation safety program can be formulated. This paper categorizes, by occupations, those populations potentially exposed to EM radiation.

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*U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, Division of Biomedical and Behavioral Science, Physical Agents Effects Branch, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

TABLE 1.—CHARACTERISTICS AND SOURCES OF ELECTROMAGNETIC-TYPE RADIATIONS

Type of radiation	Frequency range (hertz) [1]	Wave length range [1]	Energy per photon range	Typical industrial sources of exposures
Ionizing	$3^{21}\times10^{21}$ to 3×10^{16}	<10 nm	>124 eV	Medical uses, nuclear powerplants, accelerators.
Ultraviolet	3×10^{16} to 7.9×10^{14}	10 nm to 380 mm	124 eV to 3.3 eV	Lamps, welding arcs, gas discharge tubes.
Visible	7.5×10^{14} to 4×10^{14}	380 nm to 750 nm	3.3 eV to 1.6 eV	Lamps, welding arcs, hot bodies.
Infrared	4×10^{14} to 3×10^{11}	750 nm to 1 mm	1.6 eV to 1.2 meV	Lamps, welding.
Microwaves	3×10^{11} to 3×10^{8}	1 mm to 1 m	1.2 meV to 1.2 meV	Klystron, magnetron.
Radio frequencies	3×10^{8} to 3×10^{5}	1 m to 1 km	1.2 meV to 1.2 meV	Transistors, tuned circuits.

[1] The given ranges are only approximations as no exact end-point can be defined.

TABLE 2.—KNOWN HUMAN BIOLOGICAL EFFECTS FROM ELECTROMAGNETIC RADIATION EXPOSURE DEGREE OF SEVERITY

Radiofrequency and microwave radiation	Optical radiation	Ionizing radiation
Death, genetic effects, teratogenic effects, behavioral effects, cataract, acoustic response, nervous system disorders, headache, blood level changes, loss of memory, dullness, sleepiness, sinus arrthymias.	Skin cancer, squamous and basal cell epithelioma, herpes simplex lesions, cataract, retinal damage, genetic alteration, erythema, keratoconjunctivitis, heat stress, cutaneous burns, variance in biological rhythms, asthenopia.	Death, cancer, leukemia, sterility, cataract, radiodermatitis, ulcerations, erythema (burns), genetic alteration, blood cell changes, malaise, fever, nausea, weakness, shock, diarrhea, life span shortening, anorexia.

II. SOURCE OF INFORMATION

The background for this work was initiated in a previous NIOSH publication that developed a partial list of occupations exposed to certain agents, including physical agents. However, the publication did not estimate the total number of workers at risk in any EM region. Other sources of information used for this study were NIOSH reports and studies, open literature articles, U.S. Census Bureau population estimates, world almanacs, personal contacts, and certain trade organizations. In addition, details from various measurments made by the NIOSH Physical Agents Effects Branch were incorporated into this report.

III. METHODOLOGY

Using the United States Census Bureau major occupational categories charts were developed listing the various types of workers by occupational catagories. A sample chart used in the work is shown in Table 3. Extrapolations were made from 1960 and 1970 civilian workforce figures to a 1980 estimated workforce value. The results of the overall determination for these categories are shown in Table 4. Next, a judgement was made for every occupational classification within the categories to determine which EM region exposure was possible. In this decision process, the following assumptions were made:

Short

TABLE 3. Breakout of Craftsmen, Foremen, And Kindred Workers

WAVELENGTH REGION EXPOSED TO

	Male (x10³)	Female (x10³)	Total	RF	MICROWAVE	OPTICAL RADIATION NATURAL (SUN)	OPTICAL RADIATION ARTIFICIAL (LAMPS)	OPTICAL RADIATION ARTIFICIAL (ARCS)	IONIZ	
• Apparel Craftsmen + Upholsterers	98	2	100000	140000			[illegible]	[illegible]		
• Bakers	73	2	75000		75000	75000	75000	[illegible]		
• Cabinetmakers	68	2	70000	70000		70000	70000	[illegible]		
• Construction Craftsmen	3178	22	3200000							
Carpenters	900	–	900000							
Excavating, Grading, & Road Mach. OG.	400	–	400000							
Electricians	550	–	550000	550000		150000	450000		55000	
Masons + Tile Setters	205	–	205000			200000	50000			
Painters (Construction) & Paperhangers	328	2	330000			100000	300000			
Plasterers + Cement Finishers	114	1	115000			100000	[illegible]			
Plumbers & Pipe Fitters	450	–	450000	450000		175000	400000			
Other Construction Craftsmen	230	20	250000			175000	125000			
• Foreman, NEC	1840	160	2000000							
Manufacturing	1155	95	1250000				1250000	250000	250000	
Nonmanufacturing Industries	683	67	750000	160000	100000	200000	750000	200000	200000	
• Linemen + Servicemen, Tele. + Power	558	42	600000	600000	600000	[illegible]				
• Locomotive Engineers + Firemen	50	–	50000			[illegible]	50000			
• Mechanics + Repairmen	2640	60	2700000							
Air Cond., Heating, + Refrig.	160	–	160000	160000		100000	150000			
Aircraft	160	10	170000	170000	170000		170000	100000	[illegible]	
Automobile (Including Body)	1188	12	1200000	1200000			1200000	400000		
Radio and Television	158	12	170000	170000			170000		100000	
Other Mechanics + Repairmen	975	25	1000000	750000		200000	1000000	300000		[illegible]
• Metal Craftsmen (Except Mech.)	1072	58	1130000							
Machinists + Job and Die Setters	384	16	400000				400000	400000		
Sheetmetal Workers + Tinsmiths	172	8	180000				120000	180000		
Tool + Die Makers	215	25	240000				240000	240000		
Other Metal Craftsmen	290	20	310000				310000	310000		
• Printing Craftsmen	325	75	400000							
Compositors + Typesetters	107	3	110000				110000			
Pressmen + Plate Printers, Printing	180	20	200000				200000			
Other	75	75	150000				150000			
• Stationary Eng. + Power Station Ops.	95	5	100000	100000			100000			
• Other Craftsmen + Kindred Workers	2125	375	2500000	250000		800000	2000000	1200000	250000	
				[illegible]	945000	[illegible]	7020000	4500000	1455000	

TABLE 4.—ESTIMATED NUMBER OF WORKERS IN CIVILIAN LABOR FORCE BY 1980

[In millions]

Major occupational categories	Number of male workers	Number of female workers	Number of total workers	Percentage of category to total workers
Professional, technical and kindred workers	8.980	5.930	14.920	15.25
Farmers and farm managers	1.050	.050	1.100	1.12
Managers, officials and proprietors	6.797	1.523	8.320	8.51
Clerical and kindred workers	4.293	14.217	18.510	18.92
Sales workers	3.780	2.835	6.615	6.76
Crafthmen, foremen and kindred workers	12.176	.809	12.985	13.27
Operative and kindred workers	9.749	6.111	15.860	16.21
Private household workers	.030	.970	1.000	1.02
Service workers	4.770	5.930	10.700	10.94
Farm laborers and foremen	.745	.155	.900	.92
Laborers	3.420	0	3.420	3.50
Transport equipment operators	3.292	.198	3.490	3.57
Total	59.082	38.738	97.820	100.00

(*a*) Unless otherwise noted, if one worker within a particular occupational classification is exposed to a certain EM region, then all workers will be considered as being potentially exposed. This assumption will result in total estimates being higher than actual.

(*b*) The EM region chosen will best reflect the major daily insult to the particular classification in question. However, if the workers are judged to receive potential exposure from two or more EM regions, then two or more will be shown.

(*c*) Due to the difficulty in separating exposures to the optical radiation region, source descriptions are used rather than radiation region. This action is necessary since ultraviolet, infrared, and visible radiation are produced simultaneously by many sources. Furthermore, occupational exposure to the sun made it useful to classify workers' exposure by source type. Table 5 indicates the difference in exposures from natural and artificial sources. Lamps includes all types of incandescent, electric-gas discharge, and fluorescent sources while the other nomenclature refers to lasers, and various type of arcs.

(*d*) The relative risk or degree of hazard to any agent is not considered in developing the number of potentially exposed workers.

TABLE 6.—NUMBER OF WORKERS IN MAJOR OCCUPATIONAL CATEGORIES POTENTIALLY EXPOSED TO VARIOUS REGIONS OF THE ELECTROMAGNETIC RADIATION SPECTRUM

		Electromagnetic radiation region					
		Optical		Microwave and RF		Ionizing	
Major occupational categories	Number of workers in categories ($\times 10^6$)	Number exposed Percent ($\times 10^6$)	Percent	Number exposed ($\times 10^6$)*	Percent	Number exposed ($\times 10^6$)	Percent
Professional	14.920	16.340	14.7	4.180	19.8	1.791	25.9
Farmers	1.100	1.100	1.0	0	0	0	0
Managers	8.320	8.740	7.9	1.070	5.1	.290	4.2
Clerical	18.510	18.710	16.8	0	0	.300	4.3
Sales	6.615	6.945	6.2	0	0	.052	.8
Craftsman	12.985	14.625	13.1	5.615	26.8	1.450	21.0
Operative	15.860	18.705	16.8	4.725	22.4	2.391	34.6
Private HH	1.000	2.000	1.8	.200	.9	0	0
Service	10.700	15.066	13.5	2.410	11.4	.175	2.5
Farm laborers	9.000	.900	.8	0	0	0	0
Laborers	3.420	3.942	3.5	.172	.8	.262	3.8
Transport	3.490	4.200	3.8	2.690	12.8	.200	2.9
Total	97.820	111.273	100.0	21.062	100.0	6.911	100.0

*Number of people exposed may exceed the actual number of workers due to exposures of multiple agents.

Using the above assumptions and sources of information as guidelines, it was possible to proceed with the stratification of potentially exposed workers into EM regions. In many instances there was no information to guide the division process and hence "best guess" techniques were employed. For example, trying to estimate the percentage of all teachers who would be expoesed to the ionizing radiation region on a regular basis. The results of stratifying every occupational classification and totaling the results of the 12 major categories are shown in Table 6.

Finally, in the optical radiation region, the top two potentially exposed categories are the operative and the clerical workers. Each of these categories represent about 17% of the total workforce. Furthermore, it appears that almost 20% of the total workforce in this region will receive their main optical exposure from the sun, while almost all of the workforce will be exposed to lamps of some type.

IV. RESULTS

Using Table 6 it is clear that in the ionizing radiation region the operative and kindred workers' occupational category is the most potentially exposed group, followed by the professional, technical and kindred workers category. The difference between these two job categories is greater than that which exists for the top two categories in the other two regions. Over ⅓ of all the people exposed in this region are members of the operative category.

The ranking of the categories in the microwave and RF region are much closer together with the craftsman category having more potential exposures than the operative category. Almost ½ of all people exposed to microwave and RF region are members of these two categories. There are three times as many people exposed to the microwave and RF region as there are to be the ionizing region.

TABLE 5.—BREAKDOWN OF OPTICAL RADIATION BY TYPE OF SOURCE

Major occupational category	Number of workers in category ($\times 10^6$)	Number of workers exposed to ($\times 10^6$)		
		Natural source (Sun)	Artificial sources	
			Lamps	Others
Professional	14.920	1.740	14.920	0.680
Farmers	1.100	1.100		
Managers	8.320	.160	8.320	.260
Clerical	18.510	.200	18.510	
Sales	6.615	.570	6.375	
Craftsman	12.985	3.095	7.030	4.500
Operators	15.860	.665	15.835	2.205
Private HH	1.000	1.000	1.000	
Service	10.700	3.581	10.185	1.300
Farm laborers	.900	.900		
Laborers	3.420	2.459	1.453	.030
Transport	3.490	2 905	1.295	
Total	97.820	17.375	84.923	8.975

As of this date, this work has pointed out the following general conclusions:

(*a*) In many cases, workers are potentially exposed to more than just one region of the EM spectrum.

(*b*) The number of workers potentially exposed to optical, microwave/RF and ionizing regions of the EM spectrum in 1980 are estimated at 111, 21, and 7 million, respectively.

(*c*) The operative and kindred workers' category is the group which receives the greatest contribution from all of the regions. Table 7 indicates a few of the occupations making up this category. Since approximately 40 percent of the workers in this category are female, then one would expect to find many women potentially exposed to certain EM regions.

In summary this paper has made an initial attempt to estimate the number of workers potentially exposed to various regions of the EM spectrum by 1980. Obviously the absolute value of any number presented in this paper is subject to much question due to the many sources of error inherent within the stated assumptions. Nevertheless it is hoped that such an atempt, crude as it may appear, will create further thought and ultimately, better estimates. Performing a limited survey of those occupations comprising the operative and kindred workers' category would be one suggestion that might help to partially confirm estimates given in this paper. The authors invite comments and/or criticism on these estimates. In later presentations, estimations will be made on the number and type of workers actually exposed to various regions of the EM spectrum. In addition, occupational categories will be examined for typical EM sources used as well as typical exposure values. Such information could then be used to assess relative risk factors.

TABLE 7. OCCUPATIONS COMPRISING THE OPERATIVE AND KINDRED WORKERS' CATEGORY

apprentice, auto mechanics
apprentice, bricklayers and masons
apprentice, electricians
apprentice, machinists and toolmakers
apprentice, mechanics, except auto
apprentice, plumbers and pipefitters
apprentice, building trades NEC
apprentice, metalworking trades NEC
apprentice, printing trades
apprentice, other specified trades
apprentice, trade not specified
asbestos and insulation workers
assemblers
attendants, auto service, parking, gas station
blasters and powdermen
boatmen, canalmen and lock keepers
railroad brakemen, carmen
bus drivers
chainmen, rodmen and axmen, surveying
checkers, examiners and inspectors; manufacturing
conductors, bus and street railway
deliverymen and routemen
dressmakers and seamstresses, except factory
dyers
filers, grinders and polishers; metal
fruit, nut, vegetable; graders and packers, except factory
creamery, ice cream mfg., dairymen and cheesemakers
milk route delivery men
Boeing parts finishers
furnacemen, smeltermen and pourers
heaters, metal
knitters, loopers and toppers, etc.
laundry and drycleaning operatives
meat cutters, except slaughter and packing house
heavy equipment
slaughter house (etc.) butchers
milliners
mine operatives and laborers NEC
motormen, mine, factory, etc.
motormen, street, subway, elevated railway
oilers and greasers, except auto
packers and wrappers NEC
painters (except construction & maintenance) sign
photographic process workers
power station operators
divers
sailors and deck hands, seamen NEC
sawyers, sawmill workers and saw filers
sewers and stitchers, manufacturing & cutters
plywood workers
spinners, textile
rope makers
stationary firemen
railroad switchmen
taxicab drivers and chauffeurs
truck and tractor drivers
fuel oil truck drivers

sawmill truckers
lumber and logging truck drivers
moving-transfer-storage, workers and truck drivers
weavers, textile
welders and flame-cutters
operatives and kindred workers NEC
Forestry Service, Parks, etc.; lookout, game dept. workers, tree farmers
sandblasters
ordnance plant workers

ATTACHMENT D

NIOSH RADIATION PUBLICATIONS [1]

ATTACHMENT E

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
NATIONAL INSTITUTES OF HEALTH,
NATIONAL CANCER INSTITUTE,
Bethesda, Md., August 16, 1977.

Dr. WILLIAM E. MURRAY,
Chief, Radiation Section, PAEB, National Institute for Occupational Safety and Health, PHS, DHEW, Robert A. Taft Laboratories, Cincinnati, Ohio

DEAR DR. MURRAY: I am sending copies to you of the very brief comments made by Dr. Upton and by our ICRDB Program staff relating to the Franklin Institute review of the literature on radiation carcinogenesis. I have also sent the document today to Dr. Francis Mahoney who is in charge of the extramural radiation program of NCI. He will return the document with his comments directly to Mr. Dwyer.

In general, it is my feeling that this is a valuable report and reference source. We will certainly make it known through our information program.

I appreciate your interest in our program and hope that we may find ways of working together in the future.

Sincerely,

GREGORY T. O'CONOR, M.D.,
Associate Director for
International Affairs,
National Cancer Institute.

Enclosures.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
NATIONAL CANCER INSTITUTE.

Memorandum to: Associate Director for International Affairs, NCI
From: Director, NCI.
Date: August 10, 1977.
Subject: Franklin Institute Report on Ionizing and Non-Ionizing Radiation.

Thank you for letting me review the attached report entitled "A Current Literature Report on the Carcinogenic Properties of Ionizing and Non-Ionizing Radiation," prepared by the Franklin Institute Research Laboratories Science Information Services.

I regret that I have had no time to go over the report critically and in depth. On the whole, however, I consider it to be relatively good, comprehensive, and up-to-date.

Some of the flaws that came to my attention include the following:

Table 20 (page I–34): This ranking of relative sensitivities is now outdated in that the breast should be transposed to the high sensitivity category (see Upton et al., "Final Reports of National Cancer Institute Ad Hoc Working Groups on Mammography Screening for Breast Cancer and a Summary Report of Their Joint Findings and Recommendations").

Tables 36 and 37 (pages I–94, 95): The NCRP report quoted as a source has not been published and may not be published. Hence, the basis for these inferences and recommendations is not accessible to the reader for adequate documentation.

ARTHUR C. UPTON, M.D.

Enclosure.

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[1] See pp. 592–598, *supra.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
NATIONAL INSTITUTES OF HEALTH,
NATIONAL CANCER INSTITUTE.

Memorandum to: Dr. Gregory T. O'Conor, Associate Director for International Affairs, NCI.
From: Dr. John H. Schneider, ICRDB Director, OIA, NCI.
Date: August 2, 1977.
Subject: Review of the First Draft of the Document Prepared by Franklin Institute called "A Current Literature Report on the Carcinogenic Properties of Ionizing and Non-Ionizing Radiation."

Dianne and I have both reviewed this document briefly. We find the following:

(1) It appears to be quite comprehensive and detailed.

(2) The style is good and quite readable. The writer(s) is clearly an experienced professional who knows the subject quite well and knows how to express the subject matter well.

(3) The level of obvious errors is very low. Only one misspelling was found in a quick scan of many pages.

(4) The tables in section I were particularly well organized and well presented.

Minor questions:

(1) Would it be possible to increase the number of 1976/1977 references to make it appear more current? Were all available documents during the past year and a half included if possbile?

(2) The coverage of cancer causation by radioisotopes may possibly be limited. I would have guessed that there was enough data on this to give several tables listing experiments where radioisotopes were administered to animals (both acute and chronic), but I saw relatively little on this. Perhaps it should be in a separate section.

(3) The section on exposure to microwave radiation might include information about the exposure in terms of mW/sq. cm. as a function of distance and time of exposure to common microwave sources (such as microwave ovens, radiofrequency transmitters, etc.) I assume this data is available, and it may have been included, but I didn't see it in a quick scan.

(4) I am surprised that there is only one reference to Carpenter in the microwave radiation section, since I know he is considered one of the key specialists in this area.

(5) Would a brief alphabetical index be of use?

In addition, both Dianne and I would like to know:

(1) More about the number and qualifications of the people who participated in the preparation of this document. We both feel this should be reflected to some extent in a preface so that users would know how much credence to give to the document.

(2) How long it took to prepare the document and the cost of preparation.

(3) Who the specific users are expected to be and what specific uses NIOSH expects to be made of the document? There are probably several reviews or books covering each area included in this report and written by a widely recognized specialist in each specific area every year. Perhaps the document was intended to provide background for administrators or as a general reference document. In this case, the brief alphabetical index might be particularly useful.

ATTACHMENT F

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., August 23, 1977.

MR. MICHAEL J. DWYER,
Group Manager, Biomedical Projects, The Franklin Institute Research Laboratories, The Benjamin Franklin Parkway, Philadelphia, Pa.

DEAR MR. DWYER: Thank you for the opportunity to review the first draft of *A Current Literature Report on the Carcinogenic Properties of Ionizing and Non-Ionizing Radiation.*

The draft has been reviewed by several members of the Division of Biological Effects of our Bureau whose comments, which are attached, have been grouped by type of radiation, in accordance with the presentation of the material.

The document is being returned as you requested.

Sincerely yours,

JOHN C. VILLFORTH,
Director, Bureau of Radiological Health.

Enclosures.

IONIZING RADIATION CHAPTER

The writing is very clear and the organization well suited to the material. While the coverage is broad, this section is essentially a review of other reviews and, therefore, subject to selection bias both by the original reviewer and the authors of the report.

Nearly two-thirds of the Tables and Figures came from two sources, with only the order of presentation changed. Figures 5–9 and Tables 25–35 are from the BEIR report. Figures 2, 3, 13–23, and Tables 5, 7–9, 16, 19, and 20 are from Becker, in Cancer, a comprehensive treatise, which included reviews by Upton, Kellerer and Rossi, and Storer. The BEIR report attempts to fit everything to the "linear non-threshold" hypothesis. The Franklin Institute terms this approach as "administrative". The latter review provides much of the same material used by the NCRP Scientific Committee 40 in presenting the "linear-quadratic" model, with its inherent "dose effectiveness" factors. The Franklin Institute Review terms this as the "scientific" approach. The Franklin Institute definitely sides with the latter approach and doesn't differ very much in presentation or conclusions from the NCRP Scientific Committee 40 draft document. It should be noted that the NCRP document is still a draft document by one committee of the organization and has not been adopted by NCRP as a whole. The "dose effectiveness factors" concept has not yet been accepted by NCRP as policy, and indeed is still undergoing refinement as witnessed by Dr. Victor Bond's recent presentation at the Radiation Research Society Meetings.

Coverage of the epidemiologic material is incomplete and not up-to-date, and interpretations do not reflect differing viewpoints on important controversial subjects or needs for future study. Because of the method of review, with only occasional reference to original sources, findings are repeatedly attributed to reviewers rather than investigators, which makes for rather strange reading for those acquainted with the field.

A number of the cited references have been followed by later publications which are more complete or definitive.

It will be helpful to note in a Foreword the purpose of the report, method of assembling information and intended audience.

ULTRAVIOLET, VISIBLE, AND INFRARED RADIATION CHAPTERS

Comments are limited to substantive issues and impressions; the review is not therefore detailed and technical. Overall comments are summarized as follows:

(*a*) The reviewer(s) have performed an impressively thorough job of reviewing published literature, and have performed selective follow-up on some points. There is little evidence, however, that independent judgment has been exercised about validity of observation, either in the context of related research or of principles of biological organization and function. As examples of the independent judgment, we cite the following:

(1) The discussion of augmentation of mutations by caffeine and light leads to a distinction between mutagenesis and lethality which, in the current context, presents a conflict with the statement of augented mutagenesis.

(2) The discussion of photo-reactivation in human cells presents the worker's interpretation of observed phenomena as the phenomena on which the measurements were made. This distinction is considered critical by workers in the field, inasmuch as the evidence, however indirect, is scanty for photo-reactivation in human cells, and largely unsupported by independent tests.

(3) The presentation of the Forbes data on ultraviolet A and ultraviolet B interactions, and the discussion of the Bradley data on visible light effects, fail to present caveats about spectral distributions known from the sources used.

(4) The Hart and Setlow observations of tumor induction by ultraviolet are in question, by virtue of the fact that the tumors induced are well-known and associated explicitly with a microorganism contamination that was uncontrolled in the study.

(5) The information that 8-methoxypsoralen may protect against neoplasia is probably a premature judgment, on the basis of lag times for cancer induction. In addition, the reference associated with this information (Carter et al., 1976) should be re-checked—the data in the referenced paper deals with chromosome structural aberration induction. As evidence for or against radio-protective effects, the use of aberrations represents a large stretch of conditional caveats and interpretations.

(*b*) The apparent correlation between sunlight and melanoma should be included early in the section, "Types of malignancies observed in man." While data on melanoma induction with light are not as extensively reported as the data on carcinomas, they appear to have been independently confirmed.

(*c*) The considerable discussion on mechanisms of UV injury leading to carcinogenesis leads to the conclusion that the unrepaired damage is potentially dangerous. Further types of injury, now well-studied in Experimental Studies Branch (DBE, BRH) as well as other laboratories, are not mentioned. These include enhancement of cell transformation by viruses from lytic to oncogenic phases, activation of latent tumor viruses, and error-prone synthesis of DNA, or misrepair of UV damage, in which functional capacity of damaged DNA is restored via introduction of mutated sequences of bases in the DNA. It is now known that the last type of damage accounts for the majority of mutation induced in bacteria by UV radiation exposure.

(*d*) The section on co-carcinogenesis reflects the complexity, confusion, and incompleteness of the research record. It lacks some overall summation for such a perspective of current knowledge. There is a special case of what can be considered co-carcinogenesis—photosensitive people. At preesnt no mention is made of such individuals in the sense of their cancer experience and radiation protection. There exists a discussion of xeroderma pigmentosa from the standpoint of repair of radiation damage. We believe that the variability of photosensitivity, on bases other than race and pigmentation of the skin, should be included.

MICROWAVE AND RADIOFREQUENCY RADIATION CHAPTER

Comments are limited to substantive issues and impressions, so that the review is not detailed and technical. Our comments are summarized as follows:

(*a*) The discussion on cumulative effects should be reconsidered to include (1) an operational distinction between synergistic and cumulative effects, clearly stated, (2) explicit awareness that the Carpenter cataract experiments reported by Carpenter et al., 1974, as referenced, are considered by Carpenter to constitute evidence of cumulative effects, as well as by Shore, (3) additional studies on possible cumulative effects, such as Baillie at the Richmond Symposium, and (4) additional studies on possible synergistic actions, such as Lappenbusch et al., Radiation Research, 1973 and research on microwave and x-rays by Rugh and coworkers.

(*b*) No mention was found of the Prausnitz and Susskind study (IRE Transaction on Bio-medical Electronics, 1962) in which increased incidence of leucosis and leukemia in irradiated mice. While the published report can be considered incomplete with respect to a number of important details, such additional information may be available in reports to the Federal sponsor of the research.

(*c*) Because of the subject area of the review, it may be appropriate to recognize the long-term failure to follow-up on the Prausnitz-Susskind observations and therefore to list current studies in progress which are designed to examine the question of microwave and radiofrequency carcinogenesis. We know anecdotally of instances in which foci of unusual cancer are found in occupational settings; some of these are under study.

ATTACHMENT G

A Preliminary Study of National Health Hazards from Lasers

MARSHALL LaNIER,* VERNON E. ROSE, and CHARLES H. POWELL, Ph.D.†

Bureau of Occupational Safety and Health, Environmental Control Administration, Consumer Protection and Environmental Health Service, Department of Health, Education and Welfare, 1014 Broadway, Cincinnati, Ohio 45202

The techniques of industrial hygiene and epidemiology have now been combined in an effective survey procedure that permits the assessment of potential occupational health hazards associated with laser operations. Included in this assessment are such factors as the physical characteristics of the laser and laser area, the operating procedures and controls, and health services and programs available to the laser operator. Results are based on a statistical sample of the lasers in the United States and are representative of industrial, research, communication, and educational groups who are known to use lasing devices.

Introduction

AS NEW APPLICATIONS are developed, the use of laser systems in research laboratories, educational institutions, and electronic and other industries is rapidly expanding, with a concurrent increase in the number of workers exposed to the potential health hazards associated both directly and indirectly with the use of these devices. As with many research and industrial processes, the development of new sources of energy and the expanding use of these devices may be accompanied by neglect or lack of knowledge on the part of the user of the potential hazards associated with such items. Also, the basic principles associated with safe use and health protection practices involved in the operation may be neglected. This lack of understanding and knowledge of the potential health hazards is intensified when basic information relative to techniques for the evaluation and control of these hazards has not been developed. The significance of potential biologic damage from both acute and chronic exposure of workers to coherent energy from lasers, the adequacy of present methods of protection, and the magnitude of the health problem must be explored before any adequate national health program can be logically developed regarding the use of lasers. In an attempt to define, at least in part, the specific occupational health problems associated with the use of lasers, and to assess the technical assistance, research, and training required to reduce these potential health hazards, a nationwide epidemiologic study was made of laser operations. This paper reviews the results of that study.

Experimental Design

The laser survey was designed to obtain information of value to state and federal governments, the laser industry, and industrial and health organizations in evaluating the effectiveness of laser safety and health activities and in planning research programs.

The surveillance technique used is an application to a single potential source of health hazards located in many different types of industrial, medical, and research establishments of an environmental health technique developed for a national occupational health surveillance network. This network, designed to estimate the magnitude of the health problem from exposures to chemical and physical agents, has been utilized in six urban areas and in the six metropolitan counties comprising Chicago, Illinois, to assess the potential exposure of several million workers.[1,2]

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*Present address: Regional Rep., Bar. Occup. Safety & Health, Region V, Dept. H.E.W., 433 West VanBuren Street, Chicago, Illinois 60607.

†Present address: Director, Environmental Health Center, 312 Clark Hall, University of Missouri, Columbia, Missouri 65201.

The laser survey was designed to have relevance to a national occupational health surveillance network. The methodology, which has been reviewed elsewhere,[3,4] consisted of a two-part survey procedure. The first part was an interview with management. Information obtained included the major product or service of the establishment (including the state-assigned numerical code for its Standard Industrial Classification),[5] number of personnel employed both within the total plant or laboratory complex and in the laser operations, extent of general occupational health programs, health services for laser operators, medical incidents attributed to use of lasers, engineering control techniques for laser operations, etc. The general safety program was reviewed, and the health hazards related to the laser operations and the degree of engineering control known to management were recorded.

The second portion of the epidemiologic study consisted of a preliminary walk-through survey of all areas where laser systems were operated. This phase of the study was based primarily on the professional judgment of the industrial hygienists, with additional information being supplied, if necessary, by management about the laser system including make, model, type, beam characteristics, and wavelength, and standard health control operational procedures.

Warning signs, controlled access to laser operations, door interlocks, reflective surfaces, use of safety goggles, and similar health and safety procedures were evaluated.

Consideration was given by the surveyor to all environmental parameters, including chemical and other physical agents, that may have a deleterious effect on the employee or on the community from the use of lasers. It should be noted that this technique is based upon information obtained from management and on the professional judgment of the industrial hygienist making the survey; no measurements or similar evaluations were made.

The establishments surveyed included approximately 25% of all commercially built lasers in the United States,[6] and the sampling is representative of industrial, research, communication, and educational groups known to use lasers. Subscription lists of the nationally circulated trade journal *Laser Focus* were used to obtain the basic list of companies, laboratories, and individuals interested in or operating lasing devices. The data obtained from *Laser Focus* indicated that three states —Massachusetts, New Jersey, and California would probably contain approximately one-third of the commercial lasers in this country. Industrial Laser Buyer's Guides, classified section of metropolitan area telephone directories, and information obtained in some cases by county sanitarians were used to verify this conclusion and to expand the list of establishments using lasers. On the basis of this information and with the cooperation of the health and other official state agencies, an attempt was made to survey 100% of the lasers located in these three states.

Detailed instructions and carefully defined criteria were prepared to guide the surveyors in the techniques of asking questions of management and of evaluating environmental factors relating to laser operations, and to ensure maximum reproducibility of the evaluations made by the various surveyors. The requirement for subjective judgments was eliminated as much as possible, and each surveyor was given a manual containing a complete set of instructions, criteria, and guidelines.

The number of workers potentially at risk to laser energy or harmful agents in the laser areas was determined by estimation. Workers at risk, by definition, did not include other plant or laboratory personnel or similar groups who were not in the laser area, or who did not need access to the laser area to reach their normal work areas.

Where it was determined that workers were potentially exposed to laser energy, toxic agents, or harmful physical energy, the guidelines and criteria in the training manual were used to estimate the effectiveness of the control measures.

The controls or risks of hazards were determined for laser work areas, which were then judged as low-, moderate-, or high-risk areas. The following factors were considered in ranking the laser hazard: energy levels of the

TABLE I

Percent Distribution of Laser Establishments[a]

Employees Size Group	Type of Establishment						
	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
1-19	2.5	2.5	3.0	1.0	—	2.0	11.0
20-49	2.0	1.0	3.5	0.5	0.5	1.5	9.0
50-99	1.0	2.0	3.5	2.0	0.5	2.0	11.0
100-249	0.5	4.5	2.0	1.5	—	1.0	9.5
250-499	1.0	2.5	1.5	3.0	0.5	1.0	9.5
500-up	15.0	13.0	4.0	7.0	4.0	7.0	50.0
Total	22.0	25.5	17.5	15.0	5.5	14.5	100.0

[a] Grouped by type of business and number of employees.

lasers; engineering and personal controls: location, congestion, and housekeeping; number of possible exposures; requirements for direct beam viewing; potential for exposure to reflected energy; frequency of use; and other environmental factors.

Examples of factors considered in the different rankings are as follows:

1. Low-risk hazard areas
   a. Low-energy laser; no requirements for direct viewing of the beam; acceptable location with little likelihood of accidental exposure.
   b. Low-energy laser; goggles accessible and used for direct viewing of the beam; acceptable location with only a few workers in the area during laser operations.
   c. High-energy laser in supervised, closed laboratory.
2. Moderate-risk hazard area
   a. Low-energy laser; no attempt to control beam (laser movable and used in several unacceptable locations).
   b. Low-energy laser; laser location easily accessible to untrained personnel.
   c. High-energy laser; good engineering controls and personal protective devices available in open laboratory.
3. High-risk hazard area
   a. High-energy laser; inadequate engineering controls and personal protective devices in an open laboratory.
   b. High-energy laser; poor supervision, with possibility of exposures to several employees.
   c. Low-energy laser; outside work area; possibility of several exposures.

The definition of a high-, moderate-, or low-risk area states only that, in the opinion of the surveyor, the potential risk of exposure is high, moderate, or low and not that any given group of workers is presented exposed or not exposed.

The data are presented only in broad general employment groupings (using as a basis standard industrial classifications), and names of individual establishments are held confidential.

Results

Industries involved in laser use, by and large, are grouped into six major categories as follows:

1. Schools
2. Commercial research organizations
3. Instrument manufacturers
4. Electronic equipment manufacturers
5. Federal government installation and contractors
6. Miscellaneous

A total of 200 establishments constituted the sample included in this survey. The distribution of these establishments by business type and total employment size is shown in Table I. The lasers surveyed in establishments listed in the miscellaneous group included only 14.5% of the sample (Table I). The total number of the nation's commercial lasers at the time of the survey was estimated at 9400.[6] There were 2176 lasers in use in the 200 establishments included in the survey. In these establishments there was a total work force of 458,462 persons, with 279,31 working in the shop, laboratory, or plant (Table II). The majority, or 96%, of the lasers were operated in a single room or build-

TABLE II

Employees and Lasing Devices Surveyed by Type of Establishment[a]

	Type of Establishment						
	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
Number of establishments surveyed	44	51	35	30	11	29	200
Total number employees	123,873	115,324	26,921	85,674	37,498	69,172	458,462
Employees in plant, research department, or faculty	71,941	73,124	21,400	53,610	26,084	33,158	279,317
Laser operators	776	968	343	268	487	135	2,977
Total employees in laser areas, including operators	1,495	1,399	721	656	508	507	5,286
Total number of lasers	565	891	324	168	151	77	2,176
Lasers in use during survey	372	598	179	80	96	48	1,373

[a]From Powell *et al.*[4]

[illegible]. Although 42% were movable, only 3% were used both in and out of the buildings. Gas lasers were by far the most prevalent—[illegible]% of the total surveyed—and of these, 76% were continuous-wave lasers. Only 2977 employees were classified as laser operators, but because of the nature of their work, 5286 employees had access to or worked in the laser area at some time during the work day (Table II). Seventy-six percent of the lasers, [illegible]% of the laser operators, and 75% of the employees that work in or have access to the laser operational areas are employed in establishments with 500 or more employees.

Medical services provided the employees are widely (Table III). Eighty-nine percent of the establishments had an agreement with a physician to give employees emergency or other medical care, but this varied considerably with the size of the establishment. For example, 95% of all the establishments with 500 or more employees in the sample had such an agreement with a physician, whereas only [illegible]% of the establishments with 1 to 19 employees had made such arrangements. In establishments with over 500 employees, 88% had a nurse in the facility at a designated time, while only 27% of the establishments with 1 to 19 employees had made provisions for such nursing care.

Preplacement physicals were required in 67% of the establishments visited. Eighty-three percent of the organizations with more than 500 employees and 32% of those with 1 to 19 employees required such a physical examination. Those establishments requiring a medical examination of employees prior to assignment as laser operators were considerably smaller in number; only 37% of all the establishments required such a medical examination. Fifty percent of those establishments with over 500 and 9% of those with 1 to 19 employees required a medical examination prior to placement as a laser operator. Of the employees assigned to laser operations, 35% received periodic medical examinations.

Of all standard industrial classifications and employee size group establishments, 48% reported they had made provision for examination of the eyes of laser operators (Table IV). In 96% of these establishments that provided for eye examinations, the examination is given by a physician, and 86% of the examinations are given by an ophthalmologist. About 23%

TABLE III
Percent Distribution of Medical Services[a]

Type of Medical Services in Plants	Type of Establishment						
	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
Physician available for emergency or other medical care	96	90	80	87	91	90	89
Nurse in plant	93	61	32	40	64	48	58
Preplacement physicals required	64	81	37	70	91	73	67
Preplacement physical for laser operator required	18	45	26	47	64	38	36
Provision for eye examination of laser operator	23	71	40	40	64	59	48

[a] From Powell *et al.*[4]

of the university and college teaching and research groups had provisions for eye examinations; but only 18% of these establishments had a requirement for a preplacement physical examination for laser operators (Tables III and IV). University, college, and research groups had the lowest percentage for special medical services for laser operators (18% and 23%), yet 64% of the same group reported that they required preplacement physicals for all employees. This same group reported that none had specific requirements for the vision of employees who work in laser areas (Table V). Only 4 of the 36 subgroups by standard industrial classification grouping and employee size reported the same percentage for establishments which had provisions for eye examinations for laser operators (Table IV) as that for establishments which had specific criteria for the vision of laser operators (Table V). These establishments represented a total of 6% of the organizations visited (Table I). Eye damage from operating lasers was reported in 4% of the establishments. Four of the eye damage cases were of permanent injury, only three of which had been previously reported in the literature. Two other establishments reported one case each of temporary eye injury.

Using the criteria developed to evaluate high-risk areas, the industrial hygienist rated 39% of the high-energy rooms as high-risk areas. Although 32% of the people worked in rooms or areas where high-energy lasers were

TABLE IV
Percent Distribution of Establishments That Have Provision for Giving Eye Examinations to Laser Operators

Employee Size Group	Type of Establishment						
	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
1-19	40.0	20.0	0	50.0	—	50.0	27.2
20-49	0	50.0	0	100.0	0	66.6	22.2
50-99	0	75.0	57.1	0	0	50.0	40.9
100-249	0	77.7	75.0	0	—	50.0	57.8
250-499	0	80.0	33.3	33.3	0	0	36.8
500-up	26.0	76.9	75.0	57.1	87.5	71.4	59.0
Total	22.7	70.5	40.0	40.0	63.6	58.6	48.0

TABLE V

Percent Distribution of Establishments That Have Specific Vision Requirements for Laser-Area Employees

Employee Size Group	Type of Establishment: College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
1-19	0	0	0	50.0	—	0	4.5
20-49	0	50.0	0	0	0	0	5.5
50-99	0	0	14.2	25.0	0	0	9.0
100-249	0	22.2	25.0	0	—	50.0	21.0
250-499	0	60.0	0	33.3	0	0	26.3
500-up	0	30.7	37.5	28.5	12.5	35.7	21.0
Total	0	27.4	14.2	26.6	9.0	20.6	17.0

ated. the ratio of the number of people in the room to the number required was 1.59. far the greater percentage (68%) of people worked with low-energy lasers. The tendency was still to permit in the area two and one-half times the number required.

When an employee reported possible exposure to harmful levels of laser energy, 88% of the establishments required a medical examination and 86% conducted a survey or inspection of some type of the area where the [illegible] occurred. However, 95% of both the establishments with more than 500 employees and those with 20 to 49 employees required a medical examination. Fewer establishments in other employee size groups reported that they required such a medical examination. The 1- to 19-employee size group had the lowest number, with 68% of the establishments requiring such examinations.

Approximately 28% of all establishments with about 1600 employees, including laser operators and others who worked in or had access to the laser areas) maintain a medical history of the workers' previous exposures to lasers, infrared, ultraviolet, microwave, or other high-intensity light energy. The remaining workers (about 3700) covered in this survey who have access to the laser work area do not have such medical histories of previous exposures to nonionizing energy maintained by the organization for which they work. A distribution of establishments maintaining such medical histories is shown in Table VI.

The industrial hygienist was required to evaluate each laser installation by giving his opinion of overall controls and procedures according to criteria specifically developed for this survey. The results indicate that 53% of the high-energy lasers and 34% of the low-energy lasers had inadequate or marginal engineering and/or medical control procedures. The arbitrary value used to separate the high- from the low-energy laser placed 30% of the lasers surveyed in the high-energy group and 70% in the low-energy group. Operators of 62% of the high-energy lasers wore some kind of eye protection, as did operators of 25% of the low-energy lasers.

TABLE VI

Percent Distribution of Establishments That Maintain Medical History of Previous Exposures to Nonionizing Energy[a]

Employee Size Group	Type of Establishment: College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
1-19	40.0	0	0	0	—	0	9.0
20-49	0	0	0	100.0	0	0	5.5
50-99	0	0	42.8	0	0	25.0	18.1
100-249	0	22.2	50.0	0	—	0	21.0
250-499	0	60.0	33.3	16.6	0	0	26.3
500-up	20.0	50.0	37.5	35.7	87.5	35.7	39.0
Total	18.1	35.2	25.7	23.3	63.6	20.6	27.5

[a] Lasers, infrared, ultraviolet, microwave, or other high-intensity light energy.

TABLE VII
Percent Distribution of Establishments with Eye Protection and Controls for Laser Operators

	Type of Establishment						
Controls	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
Lasers used with eye protection	19.6	48.0	12.0	7.2	7.7	5.1	99.6
Goggles readily accessible	19.0	50.6	10.4	8.3	6.7	4.7	99.7
Required by company	14.5	46.2	16.0	7.4	10.6	4.9	99.6
Marginal and adequate controls	61	69	80	92	90	60	72

The distribution of eye protection used and required at the various sites can be seen in Table VII.

Warning signs were found in 51% of the rooms, warning lights in 19%, and warning buzzers in 5%. Sixteen percent of the rooms had lights and signs; 3% had lights, but no signs. There was no warning device at all in 45% of the rooms. Of the rooms with no warning devices, 33% had high-energy lasers. Of the 16% with both lights and signs, 66% had high-energy lasers (Table VIII).

Beam enclosure was not a universally used precaution for safe operation of lasers. Only 11% of the high-energy lasers operated with the beam enclosed, and only 8% of the low-energy lasers were so operated.

In general, in 79% of the establishments visited, management felt that there were hazards in working with lasers, but only 61% of the establishments provided training in laser hazards to employees.

Discussion

The industrial hygiene preliminary or walk-through survey, which was the technique employed to evaluate the potential health hazards and their control associated with the use of lasers, is designed primarily to indicate what factors contribute to or most significantly affect the problem under consideration. As such, the surveys are not designed to provide specific information about the design of control measures or the development of health services, but through interpretation by occupational health specialists, they can be use to indicate areas to which additional researc or technical evaluation efforts should be directed.

It is estimated that this survey covere only 23% of the lasers in the United State including home-built lasers. If the data obtained are extrapolated to the entire Unite States, it appears that 25,000 to 30,000 individuals work in or around laser areas an may consequently be exposed to laser energ Of primary concern in evaluating this tot figure is the fact that the work requirem for a significant percentage of the potentia exposed workers do not require that they associated with a laser. This percentage includes employees who have access to or ma pass through uncontrolled laser areas, an those who work in a room where a laser in use, but do not perform any duties directly connected with the laser operation. Th number of workers in the laser area shou be reduced to only those required for t specific operations.

In evaluating the health resources, whic include availability of a physician and nurse and an identifiable occupational hea program with preplacement and perioc physical examinations, the information obtained for laser operations is similar to th obtained in previous occupational health surveys[1,2] which were concerned with any hea hazard in the work environment. Genera results from these occupational health surv indicate that, as the plant size decreases, t

TABLE VIII
Percent Distribution of Establishments with Engineering Controls[a]

Type of Engineering Control in Laser Areas	Type of Establishment						
	College Research and Training	Business Services and Research	Manufacturer of Scientific Equipment	Manufacturer of Electronic Equipment	Government	Miscellaneous	Total
Interlocked doors to laser area	5	7	4	8	0	12	6
Laser warning signs posted in laser area	40	62	38	55	63	44	51
Laser warning lights operating in laser area	18	15	23	22	57	22	19
Laser warning buzzers operating in laser area	1	3	1	4	33	11	4
Intercom available between laser operating room and general area	5	5	5	4	5	13	5
Window covering for isolation of laser area	63	65	61	70	63	67	63

[a]From Powell *et al.*[4]

likelihood of the plant's having any components of an identifiable occupational health program also decreases. The laser survey indicated that a high percentage of the laser users were large companies (greater than [illegible] employees), and as a result there was also a high percentage of the companies which had either a partial or a complete employee health program. However, in many cases it was evident that these basic health services, especially in the areas of pre-employment and periodic physical examinations, were not being extended to laser operators. This fact suggests a need for establishments to have and use basic criteria for protecting and/or evaluating the health and safety of laser operators, with special emphasis to the eye.

The application of engineering controls to reduce the potential of exposure to laser energy was not consistent in the establishments surveyed. No one type of laser warning sign was preferred, and the percentage of establishments displaying laser warning signs was low. The use of warning signs, beam enclosures, eye-protective devices, door interlocks, etc., was more likely to be adequate in areas where high-energy lasers were in use. This indicates the need for engineering and medical controls with all laser installations. Guidelines for the application of such control measures, however, should be developed to ensure a more widespread and consistent application.

Although the actual number of reported injuries associated with the use of laser systems is small, those concerned with health and safety cannot afford to become complacent about the problem. It should be noted that the incidents of permanent and temporary injury reported in our survey were obtained on a voluntary basis and reflect the knowledge of such injuries of persons interviewed at the company surveyed. Only three cases of permanent eye damage resulting from the use of laser systems have appeared in the literature, and little information has appeared on temporary damage or on other injuries. This scarcity of recorded information, compared with the number of undocumented reports of laser injury, indicates a need for some type of laser accident reporting and evaluation system. Such a system is required to develop information for meaningful criteria and standards for evaluating the acute and chronic exposure of humans to laser energy. The need for such a system, which might be developed as a Laser Incident Repository, was expressed in the First Conference on Laser Safety, held at the School of Medicine, University of Cincinnati, on January 29–31, 1968.

Summary

The results of this preliminary survey indicate that a number of areas of medical and engineering control should be improved. Moreover, as more laser applications are developed, and as their use shifts from the research laboratory to the industrial plant and to outdoor uses at construction sites the need for more sophisticated control programs will increase. These programs are necessary (1) to protect the industrial worker in the future who may not be knowledgeable about the potential hazards associated with the laser, and (2) to reduce the risk to the general public of being exposed to potentially harmful levels of laser energy. The benefits to derived from such endeavors should ensu a safe environment for laser applications an at the same time, not adversely affect the p tential of lasers for widespread use.

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Received March 3, 1

Engineering Control of Electronic Product Radiation

The Department of Environmental Engineering, University of Florida, Gainesville, has announced the expansion of its radiological health training program into the area of electronic product radiation. In effect, the Radiation Control for Health and Safety Act of 1968 passed by the 90th Congress redefined "radiation" as any ionizing or non-ionizing electromagnetic or particulate radiation or any sonic, infrasonic or ultrasonic wave which is emitted as the result of the operation of an electronic circuit. Specifically, microwave devices and lasers are the two items which are currently receiving the most consideration.

Within the department, a new course, Electronic Product Radiation, has been added to the existing radiological health sequence. It covers the evaluation of hazards, the application of standards and the engineering of controls for these types of devices. Microwave devices, survey instruments, lasers and laser accessories are now available for research and teaching.

The program will draw support from a number of segments of the University and from local industries. Microwave engineering courses and assistance in research are available in the Department of Electrical Engineering. A graduate course in laser technology is taught by Electrical Engineering, and a cross-college graduate level course pertaining to the engineering applications of gas lasers has recently been introduced.

A limited number of traineeships will be available to qualified students during the 1970-71 academic year. Persons interested in pursuing graduate study in the area of radiological health should apply at an early date. Further information may be obtained from the Department of Environmental Engineering, University of Florida, Gainesville, Florida, 32601.

ATTACHMENT H

AN ELECTROMAGNETIC RADIATION SURVEY OF SELECTED DISPLAY TERMINALS

O. Eugene Moss, William E. Murray, Wordie H. Parr, Ph. D., Jacqueline Messite, M.D., and Gerald J. Karches
U.S. Department of Health, Education, and Welfare,
Public Health Service,
Center for Disease Control,
National Institute for Occupational Safety and Health,
Division of Biomedical and Behavioral Science,
Cincinnati, Ohio 45226

ABSTRACT

An electromagnetic radiation survey was conducted on several models and types of video display terminals (VDT) typically used in the communication field. The values obtained for x-ray, ultraviolet, visible, infrared, and radiofrequency levels were considerably below accepted threshold limit values or standards indicating that at the present time, video display terminals of the types surveyed do not present an occupational ocular radiation hazard.

I. INTRODUCTION

Visual display devices, particularly cathode ray tube displays, have been used quite successfully in military and commercial systems for many years. It is with contemporary information display procedures (i.e., graphics and data handling), however, that these visual display devices are finding their greatest application. Video display terminals (VDT) are making inroads into office managerial procedures with their ability to rapidly display letters, numbers, and other symbols. Although exact figures on the number of such devices are not available, it is estimated that between 5 and 10 million units are currently in use.[1] The number is certain to increase within the next few years as the many advantages of the VDT become apparent.

In recent years, inquiries have been received from various user groups concerning the potential hazards associated with these devices. Many VDT operators complain of such symptoms as eyestrain, visual deterioration, headaches, changes in normal visual acuity, and, in some cases, changes in color perception, dulling of sensation of fingertips, nausea, temperature and noise discomfort from equipment, and general fatigue. Recently, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Newspaper Guild and from a prominent newspaper facility to evaluate their VDT for possible electromagnetic radiation hazards to workers. This request was made after opthalmologic examinations revealed bilateral cataracts in two young newspaper employees using VDT.

II. BACKGROUND

Radiation is characterized as energy which is emitted, transmitted, or absorbed in wave or particulate form. Radiation waves consist of electric and magnetic forces which, when disturbed in some manner, produce electromagnetic (EM) radiation. The known EM radiations are grouped into a spectrum arranged by frequency and/or wavelength. The spectrum includes the radio-frequency, microwave, infrared, visible, ultraviolet, gamma, and X-ray regions. The regions are not sharply delineated from each other and, in fact, often overlap. Because of the nature of the physical and biological effects produced, it is convenient to separate these regions as shown in Figure 1.

In conducting a radiation survey, a working knowledge of the source and its characteristics is required. Basically, the VDT operates similarly to a television set. It contains a source of electrons (cathode) and a coated screen (anode) within a specially designed vacuum tube. Under high voltage, electrons are emitted by the electron gun and accelerated toward the anode. The gun scans the screen at a predetermined rate and projects electrons according to an electronically induced signal. When the electrons interact with the screen, which contains a phosphor material, visible radiation is produced and an image is formed. Several types of electromagnetic radiation are produced in a VDT. X-rays can be generated by the cathode ray tube and the shunt regulator tube. Ultraviolet, visible, and infrared radiation are emitted by the phosphor material. Radio-frequency radiation is produced by certain electronic components and circuits. Discussions with VDT desgin engineers indicated that the maximum radio-frequency radiation generated, including harmonics, should not exceed 250 megahertz (MHz).

Since most regions of the electromagnetic spectrum have been implicated as being cataractogenic, it was necessary to monitor across a broad range of frequencies to insure identification of all electro-magnetic radiation emitted by VDT. Luminance measurements were made to document the levels in regard to eyestrain. This report will describe the equipment used, present results of all measurements, discuss the significance of the results with reference to accepted exposure standards, and present conclusions. Mention of company name or product does not constitute endorsement by the National Institute for Occupational Safety and Health.

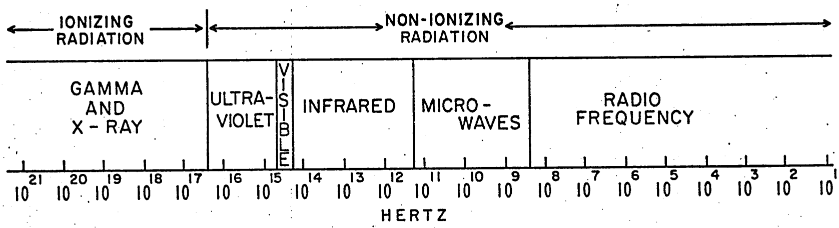


Figure 1. Regions of the electromagnetic spectrum as a function of frequency in Hertz. The division between regions are approximations as an exact division can not be defined.

III. INSTRUMENTATION AND PROCEDURE

Since it was necessary to make measurements in many regions of the electromagnetic spectrum, several types of instruments were used. A brief description of each instrument used in the survey will be given, as well as measurement details.

An EG&G Model 580/585 spectroradiometer was used to detect ultraviolet, visible, and infrared radiation in terms of power per unit area as a function of wavelength. The expression used for such measurement is spectral irradiance, and the unit is Watt per square centimeter per namometer ($W \cdot cm^{-2} \cdot nm^{-1}$). The values obtained are then summed to obtain the total irradiance for the optical region of interest. All measurements were made with this instrument at a distance of 15 centimeters from the face of the VDT screen. A collimating device was attached to the front of the detector and positioned against the screen face to minimize the effect of ambient light. Figure 2 shows the measurement set-up with this instrument.

The instrument used to measure the luminance (brightness) levels of the VDT screen and surrounding luminous environment was a spectral Mini-Spot Photometer. The value obtained with this instrument in footlamberts (fL) represents the luminance observed by an operator regardless of actual distance from the VDT screen face. All measurements with this instrument were made at a distance of one meter.

A Hewlett-Packard Model 5303B Frequency Counter was used to determine the frequency of radio-frequency (RF) radiation up to 525 Megahertz (MHz). To determine the near-field electrical component of RF radiation, it was necessary to use a special meter developed for NIOSH by the National Bureau of Standards, called an EDM-2 Electric Energy Density Meter. The EDM-2 reads out in units of joules per cubic meter ($J \cdot m^{-3}$) in the frequency range from 10–500 MHz.

The instrument used to measure the near field magnetic component of RF radiation was a Narda model 8607 magnetic field detector. This detector indicated units of watts per square centimeter ($W \cdot cm^{-2}$) in the 10–500 MHz region.

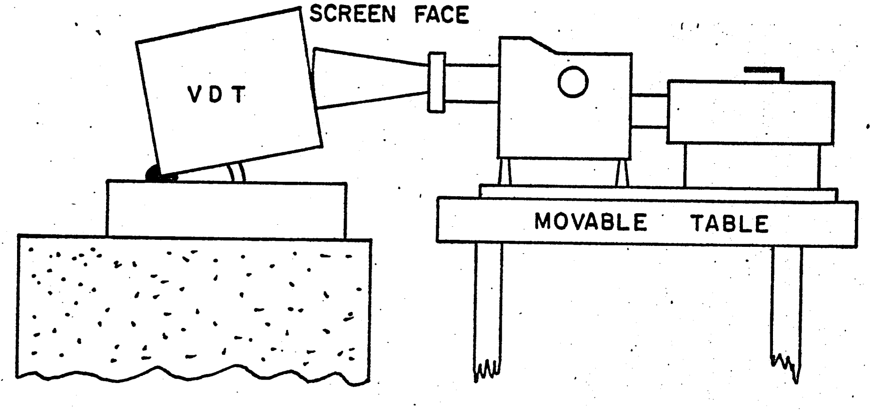


Figure 2. Schematic outline of optical radiation measurement set-up (not to scale)

Measurements of RF radiation using the last three detectors were made by slowly scanning every accessible surface of the VDT with the detectors in contact with the housing. Figure 3 indicates the overall frequency response covered by the instruments used for this evaluation compared to our best estimate of the frequencies emitted by a typical normal operating VDT.

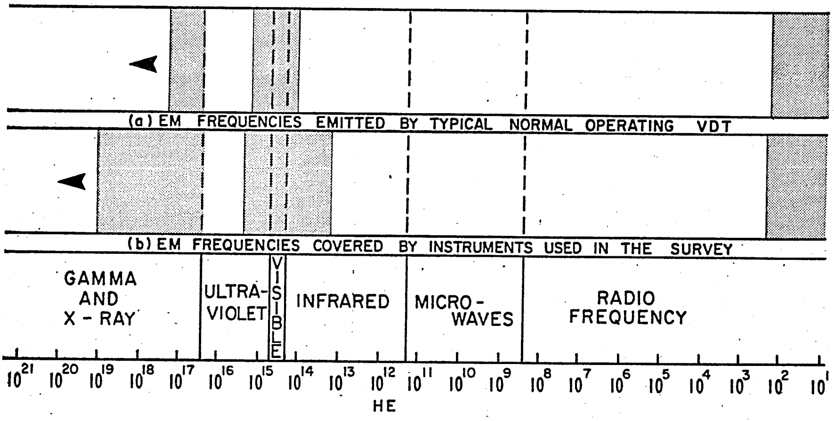


Figure 3. Comparison of EM frequencies emitted by VDT(a) and covered by NIOSH instruments(b) compared to EM spectrum.

IV. RESULTS OF MEASUREMENTS

A. Nonionizing radiation

Using the equipment described in the previous section, radiation measurements of UV, visible, IR, and RF levels were performed on three VDTs located at the newspaper facility. The terminals surveyed were a Telco Model 140 located in a wire service department, a Harris Model 1500A located in a news department, and an Incoterm SPD 10/20 used in a business department. Results of the surveys are presented for each of these three terminals. The first two treminals had been used by the employees with cataracts. In addition, selected measurements were made on numerous other terminals on various floors of the newspaper building.

1. Telco Model 40

The face of the video tube used in this terminal is 19 cm wide by 33 cm high, uses a P–4 phospher, operates at a 15–18 kilovolt (kV) tube potential, and is manufactured by Clinton Electronics, Rockford, Illinois. The terminal was located in a small room apart from other VDTs. The brightness of the tube was adjusted to a maximum and the screen filled with letters and symbols. All room lights were turned off during the survey; however, an unidentified source of electromagnetic interference made measurements difficult on several instruments.

(*a*) *UV measurements.*—The UV spectral irradiance levels for the Telco VDTs are shown in column 1 of Table 1. Notice that all measurements between 200–370 nm were recorded as zero on the 10^{-10} ampere scale of the spectroradiometer. Due to the presence of electromagnetic noise in the area, it was not possible to use the most sensitive spectroradiometer scale. The integrated UV irradiance from 200–400 nm was 2 x 10^{-9} Wcm^{-2}.

(*b*) *Visible and IR measurements.*—No visible or IR radiation was detected using the 10^{10} scale.

TABLE 1.—UV SPECTRAL IRRADIANCE MEASUREMENTS IN UNITS OF 10^{-10} W cm-2. nm^{-2}. OBTAINED FROM THE 3 VDT's SURVEYED IN THIS STUDY

	Telco 40 (1)	Harris 1500A (2)	Incoterm SPD 10/20 (3)
Wavelength (nanometer):			
200	0	0	0
210	0	0	0
220	0	0	0
230	0	0	0
240	0	0	0
250	0	0	0
260	0	0	0
270	0	0	0
280	0	0	0
290	0	0	0
300	0	.01	.09
310	0	.02	.17
320	0	.04	.30
330	0	.05	.55
340	0	.08	.87
350	0	.11	1.18
360	0	.12	1.80
370	0	.14	2.03
380	.7	.15	2.06
390	4.8	.74	2.91
400	14.6	3.65	7.30

(*c*) *RF measurements.*—Certain positions on the screenface of the VDT were emphasized during the electric field survey with the EDM–2 meter. These positions are shown in Figure 4. All readings obtained are shown in Table 2. Notice that a maximum reading of 1.2×10^{-6}J·m^{-3} was observed at the rear surface of the VDT. This RF value was about 25 times greater than the next highest reading. However, when the meter was moved 10 cm away from the rear surface, the RF value dropped to zero even when on the most sensitive scale of 3×10^{-9}J·m^{-3}. The magnetic field measurement using the Narda 8607 meter registered zero on its most sensitive scale of 2×10^{-4}W·cm^{-2}. On this particular VDT, no frequency higher than 2 MHz was recorded. Consequently, none of these readings have real significance since these meters are not designed for measuring frequencies below 10 MHz.

(*d*) *Luminance measurements.*—On the Telco 40 VDT, the brightness values ranged from 1.5 to 2.5 fL for minimum and maximum luminance levels, respectively.

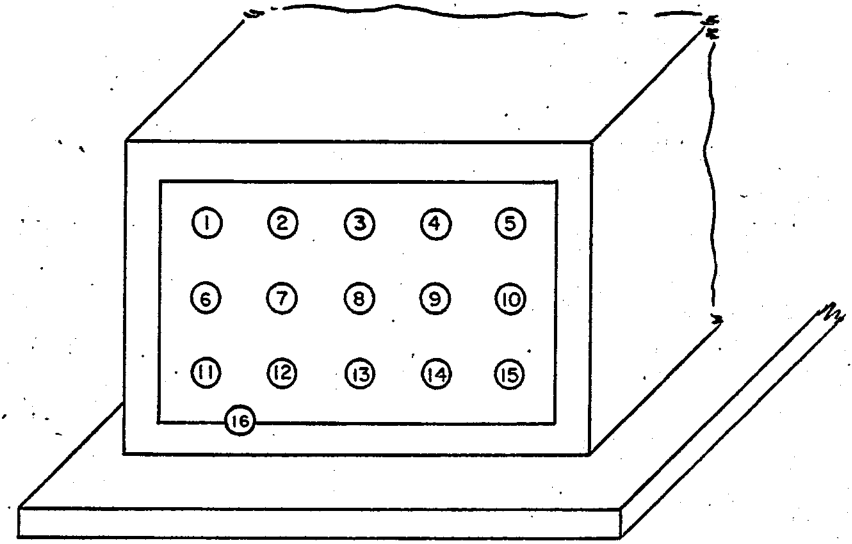


Figure 4. Electric field strength monitoring points on VDT screen face.

TABLE 2.—ELECTRICAL FIELD STRENGTH MEASUREMENTS OF THE TELCO MODEL 40 VDT

Location:	Maximum reading ($10^{-6}Jm^{-3}$)*		Maximum reading ($10^{-6}Jm^{-3}$)*
1	0	11	.005
2	.023	12	.003
3	.025	13	.010
4	.027	14	.010
5	.015	15	.010
6	.020	16	.050
7	.030	Top	0
8	.010	Right side	.003
9	.010	Left side	0
10	.010	Rear	1.2

* Can convert into Vm^{-1} using conversion $Vm^{-1}=475.3-wJm^{-3}$

2. Harris 1500A

This VDT is one of the more common models used in the newspaper business. The video screen has a square viewing area of 25 cm×25 cm, uses a P-31 phosphor, the video tube operates at a 23-33 kv potential, and is manufactured by Thomas Electronics, Inc., Wayne, New Jersey. As with the first VDT surveyed, the brightness control was adjusted to maximum and the screen filled with a typical message. Because of the size of the room and the numerous ongoing plant operations, it was not possible to eliminate ambient room light during measurements on this unit.

(*a*) *UV measurements.*—The UV spectral irradiance levels for the Harris 1500A are shown in column 2 of Table 1. The integrated UV irradiance from 200 to 300 nm was zero, and from 300-400 nm was $5.1\times10^{-10}W\cdot cm^{-2}$, as measured on the most sensitive scale.

(*b*) *Visible and IR measurements.*—No visible or IR radiation was detected on the most sensitive scale of the spectroradiometer (i.e., 10^{-11} Amperes).

(*c*)*RF measurements.*—A 27 MHz frequency was registered by the frequency counter at the surface of the unit. This signal was not detected when the counter was approximately 12 cms from the unit. The EDM–2 and the Narda 8607 registered zero on their most sensitive scale ($3\times10^{-9}J\cdot m^{-3}$ and $1\times10^{-4}W\cdot cm^{-2}$, respectively) next to the VDT housing. All measurements were conducted in the same manner as with the Telco VDT.

(*d*) *Luminance measurements.*—The luminance values ranged from 2 to 10 fL at the minimum and maximum brightness, respectively.

3. Incoterm SPD 10/20

This VDT has a tube face measuring 16.5 cm wide by 23.9 cm high, uses a P–39 phosphor, operates at a 12–14 kV potential, and is manufactured by Ikegami Electronics, New York City. All measurements were taken at maximum brightness with a filled screen in room light.

(*a*) *UV measurements.*—The UV special irradiance levels for the Incoterm VDT on the most sensitive scale are shown in Column 3 of Table 1. The integrated UV irradiance from 300–400 nm was $1.9\times10^{-9}W\cdot cm^{-2}$.

(*b*) *Visible and IR measurements.*—No visible or IR radiation was detected on the most sensitive scale.

(*c*) *RF measurements.*—A 20 MHz frequency was detected by the frequency counter when held in contact with the VDT housing on the right side. This signal was not detected when the counter was 10 cm from the unit. As in the case of the Harris 1500A both the EDM–2 and Narda 8607 registered zero on their most sensitive scale during the Incoterm survey. All measurements were conducted in the same manner as described previously.

4. Measurements made on other VDT units

RF and luminance measurements obtained on randomly selected VDT units at the newspaper facility generally confirm those values reported for the above three VDT units. Table 3 reflects luminance measurement made on these 22 VDT units. All RF magnetic and electric field measurement, made on these 22 units, were zero on the most sensitive detector scale. In making measurements on a VDT on a higher floor, a RF level of $1\times10^{-3}W\cdot cm^{-2}$ was obtained. With the terminals de-energized, the reading still persisted. From this it was concluded that the source of radiation was not VDT related. Since readings of the same magnitude were obtained in the adjoining computer area, and at nearby windows, it was postulated that signals from nearby TV and radio stations were directly exciting the detectors.

TABLE 3.—ADDITIONAL LUMINANCE MEASUREMENTS OBTAINED FROM RANDOMLY SELECTED VDT UNITS DURING SURVEY

Model	Number of units surveyed	Range of maximum brightness (footlambert)	Range of minimum brightness (footlambert)
Harris 1500A	13	4–21	1–3
Telco 40	4	3–5	1–2
Harris 2200	4	3–5	2
IBM 3277	1	7	6
Total	22	3–21	1–6

B. Ionizing Radiation Measurement Results

1. Background

Numerous X-radiation surveys have been reported on various VDT makes and models. The findings in every one of these surveys has revealed that X-ray levels emitted by VDT rarely exceed background. For example, in 1970 and 1972, Dr. Walter Mauderli made measurements on the same Harris 1100 VDT in Florida to determine if radiation levels increase as a function of VDT age.(2) His conclusions were: any aging effect, if it existed at all, "would have the tendency to shift the energy spectrum of the produced X-rays to lower values—thus reducing the penetrating power of the radiation." He also stated that no readings could be found which exceeded the natural background level. In 1973, Mauderli made a radiation survey on a Harris 1500 VDT and concluded that the unit has an X-ray output level at any accessible location which was below 0.02 $\mathrm{mR{\cdot}hr^{-1}}$. Also, in 1973, the U.S. Department of Labor made X-ray measurements on two Harris VDT at United Press International's newsroom in New York City and found radiation levels on the order of background radiation.(3) In 1974, the State of Maryland made an X-ray survey on 74 different VDTs at the Baltimore Sun plant.(4) Their report stated, "In no case did the level found exceed the background radiation level. That is to say, the X-radiation produced by the VDTs was essentially zero."

NIOSH, in 1975, was asked to perform an X-ray survey at the same newspaper facility. The radiation results from this survey were obtained using a Victoreen Model 440 RF/C X-ray survey meter. This meter is shielded against response to RF radiation and measures low energy X-rays in units of milliroentgens per hour ($\mathrm{mR{\cdot}hr^{-1}}$). Background readings taken at frequent intervals ranged from 0.16 to 0.70 $\mathrm{mR{\cdot}hr^{-1}}$. Readings from an internal calibration source were also recorded to insure the meter was functioning properly throughout the measurements.

All measurements were performed by slowly scanning over the display screen, which was filled with letters and symbols, as in a normal operation. Approximately 20% of the VDTs were measured on all 6 sides with the remaining VDTs being surveyed on all sides except the bottom. The gross X-ray levels recorded ranged from 0.12 to 0.85 $\mathrm{mR{\cdot}hr^{-1}}$. The unit with the highest momentary value recorded (0.85 $\mathrm{mR{\cdot}hr^{-1}}$) was rechecked at the conclusion of the survey and a reading of 0.20 $\mathrm{mR{\cdot}hr^{-1}}$ was obtained. When these levels are compared with background readings, it is apparent that no measurable radiation was observed. Table 4 indicates the range of X-ray levels, in $\mathrm{mR{\cdot}hr^{-1}}$, measured on the various VDT types.

In 1977, a major insurance company surveyed 67 VDTs at the same newspaper facility where measurements were made for this study.(5) The maximum X-ray level measured at the screen face from all these units was 0.2 $\mathrm{mR{\cdot}hr^{-1}}$. The VDTs surveyed at that time were made up of the following models: Harris 1500A, Harris 1520, Data Speed 40, Data Disc 66121, and IBM 3277. The insurance company indicated that, since the background ranged from 0.1 to 0.3 mR·hr, then no measurable X-ray radiation was being emitted.

No X-ray measurements were made during the present survey for two reasons. First, the X-ray results from the insurance company and NIOSH measurements indicate no X-ray emission on similar VDTs, both at the same and another newspaper plant; and second, the results of X-ray measurements made by other groups indicated no occupational exposure when properly shielded, as specified by the manufacturers.

TABLE 4.—X-RAY EXPOSURE LEVELS FOR VDT'S

VDT type	Number of units surveyed	Range of X-ray levels ($\mathrm{mR{\cdot}hr^{-1}}$)	
		Maximum	Minimum
Harris 1500A	75	08.5	0.13
IBM 3270	39	.25	.12
Infrarex 1303	11	.22	.14
Background		.70	.16

V. DISCUSSION OF RESULTS

This section discusses results of pertinent electromagnetic radiation measurements and of medical examinations conducted at the newspaper facility.

A. Electromagnetic radiation results

The potential electromagnetic radiation hazards from the VDTs surveyed in this report may be evaluated by comparing the maximum observed reading in any of the regions with currently accepted standards. Table 5 summarizes this information. Observe that, in this table, all values reported are below current safety standards. The use of the symbol ND in the table indicates that energy levels were too low to be detected by the appropriate instrument on the most sensitive scale. All measurements were obtained with the detector probes in contact with the VDT screen face. This means that even these low "emission" levels must be further reduced by geometrical consideration in order to characterize the exposure at the eye position of the operator, typically 0.5 to 1 meter away. Thus, it is appropriate to state that radiation levels 0.5—1 m away from the VDT will be even lower than those values which appear in Table 5.

Therefore, based on the above measurements, the current standards, and present knowledge of biological effects, the VDTs surveyed do not appear capable of producing cataracts or even present an occupational ocular radiation hazard.

TABLE 5.—COMPARISON OF MAXIMUM VDT RADIATION LEVELS MEASURED AT THE SCREEN FACE WITH CURRENTLY ACCEPTED STANDARDS

Radiation region	Maximum VDT measured level	Occupational exposure standard	Reference
Ultraviolet	2×10^{-9} Wcm^{-2}	1×10^{-3} Wcm^{-2}	NIOSH CD (6).
Visible (luminance)	21 fL	2.92×10^{3} fL	ACGIH TLV (7).
Infrared	ND*	10^{-3} Wcm^{-2}	ACGIH TLV (7).
RF—Electric field strength	ND*	2×10^{2} Vm^{-1} 5×10^{-1} Am^{-1}	ANSI (8).
X-ray	0.85 mRhr^{-1}*	2.5 mRhr^{-1}*	OSHA (9).

*Not detectable.
†Includes background level.
‡ Based on the average annual dose limit of 5,000 mR divided by 2,000 working hours per year.

B. Medical results

The two workers with cataracts, one a 35-year-old male and the other a 29-year-old male, were interviewed, and detailed occupational and medical histories were obtained. In addition, their medical records at the newspaper medical department were reviewed. Reports of ophthalmological examinations in 1977 by two opthalmologists were also obtained. In addition, in the case of the 29-year-old male, reports were received of four opthalmological examinations performed between November 1970 and February 1976 by an opthalmologist who is now deceased. The duration of exposure to VDT units at the newspaper by the two workers had been approximately four months for the 35-year-old male and one year for the 29-year-old male. In addition, the 29-year-old worker was exposed during a three month training period (approximately one hour per day for a few days each week) beginning late November 1975. Both of the opthalmologists who examined the two works in 1977 reported finding bilateral posterior cataracts. In addition, the 35-year-old male was noted to have evidence of some retinal degeneration. Attempts to obtain records of previous opthalmological examinations on this worker have not been successful, to date. However, the reports of the previous opthalmological examination on the 29-year-old male showed the first indication of a posterior polar cataract in the right eye on February 26, 1976, a time coinciding with the onset of his continuous daily exposure to the VDT units. (As noted previously, there was a training period of brief intermittent exposure over about three months before he used the units on a regular basis.)

The cataracts found are compatible with those reported from exposure to radiant energy, but they are also compatible with those seen congenitally or those associated with other etiologies, such as diabetes or steroids. However, the workers' medical histories did not disclose any pertinent information to suggest any such etiologies for the cataracts. Since the survey did not indicate any significant occupational electromagnetic radiation levels, the etiology of the cataracts remains undetermined.

Estimates of the incidence of cataract in the United States by age and sex range from 330,000 to 900,000 cases per year[10]. With this many people estimated to develop cataracts, it would not be alarming to find quite a few people developing cataracts in a subset of VDT workers. At present, incidence estimates for bilateral cataracts are not available. Therefore, the above figures have to be viewed conservatively. Interestingly enough, the incidence of cataracts for women is considerably higher than for men.

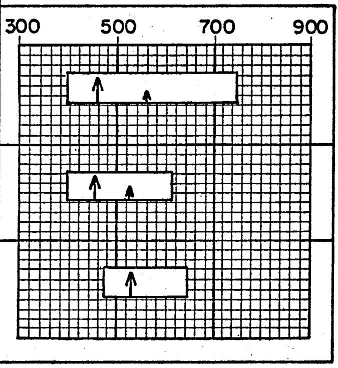
VI. ADDITIONAL DISCUSSIONS

A. Phosphors

Information can be viewed on a VDT because of the manner in which electrons interact with the phosphor coating present on the screen of a cathode ray tube. Phosphors are chemical substances which exibit fluorescence (i.e., emit visible light) when excited by ultra violet radiation, X-rays, or an electron beam. The amount of visible light produced by a phosphor is proportional to the amount of excitation energy. Every phosphor has a property that allows it to emit light for a very short time after the excitation energy has been removed. This particular property is called persistence, and is extremely important in viewing information presented on the screen. Table 5 indicates some of the characteristics of the phosphors generally used in VDTs, and specifically those encountered in these measurements. The open blocks containing the arrows represent the spectra associated with the given phosphor. The arrows indicate the position of spectra peaks. Notice that the spectra output of these phosphors is limited to a fairly narrow spectral range. Much of the work done in categorizing phosphor properties has been performed by the Joint Election Device Engineering Council (11).

Table 6 confirms our findings that very little UV radiation can be emitted by the VDT. As explained earlier, the level of visible radiation emitted by the phosphors was below the detection limit of the spectroradiometer. Furthermore, the table substantiates the fact that no IR radiation could be detected (since none is emitted). Finally, no measurements were observed which would suggest an increased radiation level of any type as a function of age of VDT. Not every phosphor made is classified in Reference 11; however, most of the phosphors used in VDTs are catalogued and referenced by the organization (11). Using that reference, a spectral energy distribution was made of all phosphors listed, as of November 1975, and is shown in Table 7.

Table 6. Spectral characteristics of phosphors found in VDTs measured in this report (2).

PHOSPHOR DESIGNATION	WAVELENGTH OF PROMINENT SPECTRAL PEAK		SPECTRAL RANGE (nm)
	MAXIMUM	OTHER	
P4 (SULFIDE)	460	560	
P 31	520	455	
P 39	525	—	

As can be seen from this list, only three phosphors emit in the IR, while 25 emit in the UV. All IR emitting phosphors in the list produce considerably less than 20% of the total optical spectrum in the IR. With the exceptions of P-15, P-16, and P-47, most of the UV emitting phosphors also produce very little of their total optical spectrum in the UV region (the average is 10-20%). Such a list could be of value in possibly averting any future concern associated with optical radiation.

B. Eyestrain

After reviewing the literature on VDT, it does not appear that any specific occupationally-induced disease has, to date, been documented that implies the VDT as the causative agent. However, complaints of eyestrain (aesthenopia) often are voiced. Eye fatigue and associated symptomatology experienced by people working on VDTs may be similar to the fatigue encountered by workers

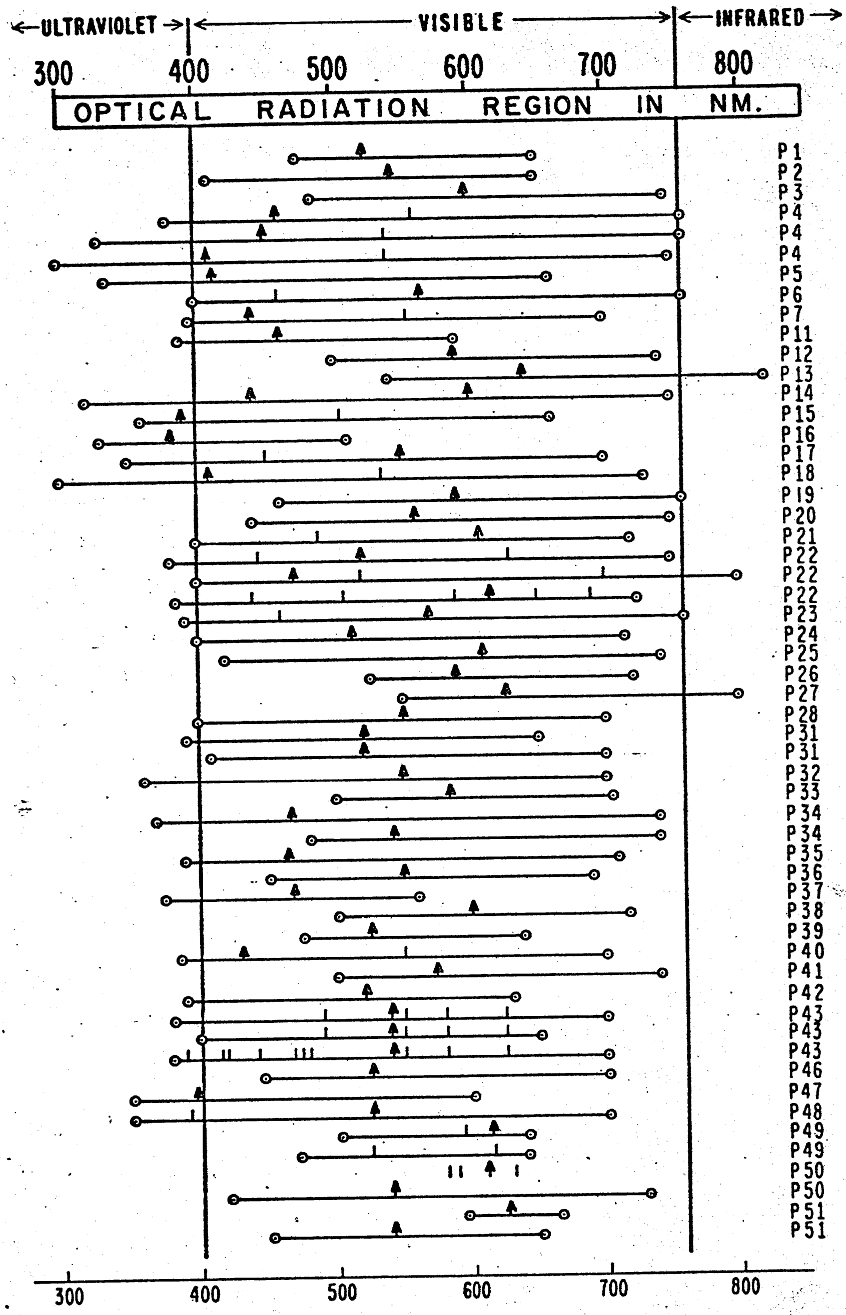


TABLE 7. Estimated spectral energy distribution characterisics of all phosphors modified from JEDEC A/O November 1975.

in other occupations (12). Many factors related to the worker, such as his visual acuity, the task to be done, the VDT itself, the work environment, and the background lighting, will affect the probability that an individual will experience the above symptoms. Obviously work posture, equipment layout, age of worker, length of time spent on VDT, environmental lighting, presence of eye glasses or contact lens, use of antireflection coatings, and latent visual defects are a few factors which will affect the incidence of eye fatigue. However, with many VDTs in use, the number of complaints could be quite large. Attention should be focused in this area on more definitive studies. Some research has been performed by the Armed Services (i.e., air traffic controllers) and by VDT manufacturers. Two excellent reviews of this subject were prepared by Hart (13) and Ostberg (14).

C. Other Measurements

Very little published information was available on VDT radiation levels and measurement techniques, prior to the NIOSH involvement. After obtaining the results presented in this report, and discussing the related problems with many people, several additional measurement exercises to validate these results were conducted by nongovernment facilities. NIOSH has reports from two different facilities examining different VDT models. These reports essentially confirm the data presented in this report. A small difference exists in the numbers obtained in measurements, but in no case did any VDT unit come near exceeding the recommended standard. Frequencies were identified by using a freqency analyzer, with none being detected above a 250 MHz limit, as previously identified by NIOSH.

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ATTACHMENT I

MORTALITY AND INDUSTRIAL HYGIENE STUDY OF WORKERS EXPOSED TO MICROWAVES AND RADIO FREQUENCY ENERGY

The past 50 years have brought a rapid proliferation of the uses for electromagnetic radiation. Today electromagnetic radiation emanates from radar, television, communication systems, defense systems, microwave ovens, industrial heat treatment systems and medical diathermy units. In spite of this rapid proliferation of electromagnetic wave length equipment very little research has been conducted in the U.S. to investigate the long-term health effects on low-level microwave radiation on humans. The consequence of undervaluing or misjudging the biologic effects of long-term, low level exposure could become a critical problem for occupational health.

Recent evidence indicates that the development of cancer at certain sites may be associated with exposure to electromagnetic radiation. At a naval air station at Quonset Point, Rhode Island, 3 civilian employees among a group of 8 technicians who were engaged in the overhaul and repair of Tactical Airborne Navigation Equipment (TACAN) have either developed cancer or died of it since 1970. Two of the men (age 31 and 35) developed pancreatic cancer which is very rare considering that 99% of all reported cases occur in people over 40. These 2 men worked side by side at a test bench at Quonset Naval Air Station for several years. NIOSH plans to conduct a retrospective mortality study to further investigate the health effects resulting from long-term, low-level exposure to electromagnetic radiation.

Following site visits at the Naval Air Rework facilities, NIOSH has identified a cohort of workers who may be suitable for inclusion in an epidemiologic study for determining the health effects resulting from long-term, low-level exposure to electromagnetic radiation. This population would consist of all persons enrolled in the electronics apprenticeship training program which has been sponsored by the U.S. Navy since the early 1950's. However, since this cohort will consist of only about 800 individuals, additional walk-through surveys and record assessments will be conducted in both DOD and private industry before a final study population is selected.

Recent NIOH measurements in the TACAN job operation at several naval bases revealed that the present x-ray and microwave radiation levels are currently within the OSHA recommended standards. There is little environmental data available on the past levels of radiation exposure in these job categories.

Protocol For Mortality Study

I. INITIAL RESEARCH

A. Literature searches.
B. Walk through surveys for record assessment and process familiarization.

II. SELECTION OF COHORT

A. Criteria for Selection.
  1. A significant proportion of the population has sufficient latency since onset of exposure.
  2. Suitable demographic and occupational history data for study.
    a. Name
    b. SSN
    c. Date of birth
    d. Sex
    e. Beginning date of employment
    f. Ending date of employment
    g. Detailed occupational history by job and operation (optional)
    h. Last known address (optional)
B. Microfilm all records.

III. BUILD MASTER FILE

A. Code data for computer
B. Verify coding
C. Edit master file
D. Obtain error free master file

IV. VITAL STATUS ASCERTAINMENT

A. Active code alive
B. Inactive
  1. Federal agencies follow-up
  2. State Agency follow-up
  3. Local records follow-up
  4. Case location contract for follow-up

V. MORTALITY AND MORBIDITY INFORMATION

A. Obtain death certificate for those indicated as deceased.

B. Obtain medical information on all deceased individuals through hospital pathology records and medical histories to include smoking.

C. Pathological material will be collected when warranted by investigator to verify diagnosis.

D. Code deaths by the International Classification of Diseases.

VI. ANALYSIS

A. A modified life table analysis to obtain person-years at risk for specific causes of death by five-year age groups and number of years after initial exposure will be developed.

B. Comparisons of observed deaths by specific causes will be made using both United States and local geographic rates to generate the expected.

C. A final report will be written to include mortality, morbidity and environmental data with subsequent recommendations.

INDUSTRIAL HYGIENE PROTOCOL

1. Conduct extensive literature searches regarding physical hazards and specific toxic agents to which workers are exposed to determine current state of knowledge for sampling and analytical methods, past environmental investigations and other related technology and information required to design, conduct and evaluate the results of industrial hygiene studies.

2. Locate industries where the physical hazards or toxic agents under study are used, made or found as by-products. Select industries where representative worker exposures to the specific toxic agent or physical hazard may be expected.

3. Conduct preliminary industrial hygiene surveys, including environmental sampling in preparation for indepth industrial hygiene surveys. Coordinate preliminary surveys with other Sections and Branches within DSHEFS and with other Divisions within NIOSH, as appropriate.

4. Develop detailed written protocol of in-depth industrial hygiene studies including consideration of statistical design; the proper use of the environmental data base; definition of equipment needs to perform the study; delineation of sampling procedures and specification of other related steps required to satisfactorily complete the study.

5. Conduct in-depth industrial hygiene studies in work places including the documentation of past exposures; description of the work procedures and practices; collection of environmental samples; development of job dictionary based on job descriptions in the work place; collection of data on sample sheets for use in environmental data base; and other steps required to produce accurate environmental data.

In-depth study should:

(*a*) Describe the operations and determine the number of workers exposed in the facility. Identify job types for workers and obtain or develop specific job descriptions for each. Obtain raw materials and product lists with respective quantities that relate to worker exposure. Provide photographs and sketches to document existing conditions.

(*b*) Document past and present work practices; industrial hygiene practices, including utilization of protective clothing (i.e. type, frequency of change, laundering practices); protective devices (i.e. respirator usage, type, maintenance); housekeeping practices; shower requirements, eating, smoking and drinking practices in production areas and relevant process or production changes which may relate to past and present worker exposure to the agent under study.

(*c*) Collect personal and area samples to determine the eight (8) hour daily time weighted average and peak concentrations of the agents to which the workers (by job-type) are exposed. Area samples will be taken in areas of suspected high concentrations. Sampling and analysis will be done in a manner consistent with good industrial hygiene practice to provide statistically valid data that are representative of present worker exposures (categorized by different job-types).

(*d*) Describe ventilation systems including design information, appropriate measurements, dates and extent of system changes, and how they relate to past and present worker exposures to the agent under study.

6. Analyze and interpret results from indepth industrial hygiene studies using statistical methodology where appropriate and in terms of job category. Relate environmental findings with data from health effects studies.

7. Prepare detailed technical reports describing the results of literature searches, preliminary industrial hygiene surveys and indepth environmental studies. These reports will be coordinated with other Sections, Branches, and Divisions within DSHEFS.

ATTACHMENT J

RF/MICROWAVE TERATOGENIC STUDIES

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Senator STEVENSON. Our final witness is Dr. David Rall, Director, National Institute of Environmental Health Sciences, accompanied by Robert Miller and Donald I. McRee.

You may summarize your complete statement if you like.

STATEMENT OF DAVID RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES; ACCOMPANIED BY DONALD I. McREE, RESEARCH PHYSICIST; AND ROBERT W. MILLER, CHIEF, CLINICAL EPIDEMIOLOGY BRANCH, NATIONAL CANCER INSTITUTE

Dr. RALL. Thank you very much, Mr. Chairman.

I will indeed summarize.

Senator STEVENSON. The full statement will be placed in the record.

Dr. RALL. I am pleased to introduce Dr. Robert Miller, Chief of the Clinical Epidemiology Branch, NCI, and on my left, Dr. Donald McRee, research physicist, National Institute of Environmental Health Sciences.

The NIH is the Nation's principal instrument for both the support and conduct of research in the biomedical sciences.

However, even in such a broadly based effort, there must be concern with the careful selection of research areas.

Thus, when the Atomic Energy Commission, now ERDA, and I gather soon to be the Department of Energy, was created and as part of its mandate began to develop a strong program in biology and medicine related to ionizing radiation, NIH made the decision to move into this area only when it was critical to specific needs of NIH Institutes.

Let me add one historical note. Prior to World War II, the NCI had a strong radiation biology program. Dr. Egon Lorenz, one of the first members of the National Cancer Institute, was a leader in research on the carcinogenic effects of ionizing radiation.

His studies pioneered efforts to understand the biological effects of long-term exposure of large numbers of animals to low doses of environmental pollutants—specifically X-rays.

The first clear demonstration that physicians occupationally exposed to X-rays had a higher incidence of cancer was by Henshaw and

Hawkins of NCI in 1944. This group was joined in the mid-1940's by Dr. Alexander Hollaender. Later on Dr. Hollaender was detailed to the Manhattan project at Oak Ridge and ultimately became, in the early 1950's, the first Director of the Biology Division of the Oak Ridge National Laboratory.

When the NIEHS was created, we reviewed the status of research in environmental factors and identified nonionizing radiation as an area which was receiving inadequate research attention.

Thus, we proposed to develop a program to study the biomedical effects of nonionizing radiation in this area.

Last year the House Committee on Appropriations directed the NIEHS to undertake a study of research needs in environmental health.

This study, undertaken with the participation of more than 80 scientists from Government, industry, and educational institutions, was submitted to the committee in connection with its review of the 1978 budget.

Chapter five of the report addresses the broad issue of physical environmental factors and makes recommendations regarding research needs in this field including nonionizing radiation.

With the committee's permission, I would like to submit that chapter for inclusion in the record at this point.[1]

Senator **Stevenson**. It will be retained in the committee's files.

Dr. **Rall**. A number of the NIH Institutes are conducting research on the use of ionizing radiation as a diagnostic or clinical tool.

For example, the National Institute of Neurological and Communicative Disorders and Stroke has established that computerized axial tomography—CAT—scanners are effective and when used appropriately and with restraint can provide a valuable diagnostic alternative to some other neurological diagnostic procedures which have greater risk associated with their use, such as carotid angiography, cerebral pneumograms, and, to some extent, the isotope brain scan.

The National Cancer Institute supports and conducts research concerning the use of therapy with ionizing radiation. The NCI is studying methods to reduce radiation exposure during diagnostic tests, and is investigating the possible replacements for ionizing radiation diagnostic methods for such problems as brain, breast, and lung tumors.

The National Institute of General Medical Sciences supports a variety of research projects aimed at the development of new radiation detection and imaging systems, development of computerized methods of interpreting radiologic images, and the development of new radio pharmaceuticals.

As indicated earlier, the broad area of environmental and human health effects of ionizing radiation is the primary responsibility of ERDA and the NIH has deferred to that agency in this area.

NCI and NIEHS are, however, conducting and supporting epidemiological studies to determine if groups of patients exposed to diagnostic or therapeutic radiation (for example, radiotherapy for ringworm of the scalp and radioactive iodine thyroid uptake studies) show long-term health effects.

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[1] See Human Health and the Environment—Some Research Needs, Report of the Second Task Force for Research Planning in Environmental Health Science. DHEW Publication No. NIH 77-1277.

NCI and NIEHS supported the large-scale studies that defined the lung cancer risk for uranium miners.

NCI has provided support for important new programs at the Atomic Bomb Casualty Commission.

In contrast to ionizing radiation, NIH and particularly NIEHS is committed to develop research aimed at broad understanding of the health effects of microwaves.

The NIEHS supports and conducts most of the NIH research in this area. However, due to limited laboratory space and resources, the Institute has only been able to expose small biological systems to a constant field of microwave irradiation.

Because it is important to know the dose of the exposure in order to correlate the incident exposure to the absorbed energy, our scientists have developed systems with well characterized microwave fields.

A refinement of the NIEHS exposure system is that the biological specimen is located inside environmental or constant temperature chambers which allow us to control the temperature and humidity while the biological specimens are being irradiated. This provides the opportunity to look at electromagnetic field effects separated from gross heating of the specimens.

In order to correlate any biological effect with absorbed microwave energy, it is important to accurately characterize the amount of energy that the biological system is exposed to.

Thermocouples or metallic devices used to measure the energy absorption perturb the fields being measured. NIEHS scientists have developed small thermistor probes, liquid crystal fiber optic probes, and infrared thermography which can accurately measure energy being deposited in biological systems, but which do not disturb the system.

Other work we are involved in includes research on the effects of microwaves on teratology (birth defects), fertility and immunology.

On exposing developing embryos to microwave radiation throughout the developmental period a level of 5mW/cm^2, no gross deformities were measured if the temperature was not allowed to rise above normal developmental levels.

However, small but statistically significant effects on hemoglobin and white cells numbers were measured.

In addition, our scientists are investigating basic interaction mechanisms and the effects of microwaves on neural response.

NIEHS is in the process of building a permanent research facility. This facility will contain specially designated laboratory space for our biophysics laboratory. We anticipate that when this becomes available in early 1980, we shall significantly increase our in-house research on the biological effects of nonionizing radiation.

Currently, we are expanding contract research, and, at the Universities of Washington and Utah, we are sponsoring research aimed at determining the effects of long-term, low-level microwave exposure; at the University of California at Los Angeles, work with 60 cycle fields (similar to power line electric fields); and at the Jefferson Medical College research aimed at determining the pre- and post-natal effects of microwave irradiation.

This concludes my summary statement. We shall be happy to answer any questions you may have.

Thank you.

Senator STEVENSON. Thank you.

You mentioned the research on powerline electrical fields. How far along is that?

Dr. RALL. Dr. McRee?

Dr. McREE. The work we are supporting is going into the second year of that research. The research is to determine the behavioral effects of extra low frequency radiation as well as blood chemistries assocated with neurological effects and also the effects on neural tissue.

The University of California has measured the effects of ELF, low-frequency fields of calcium efflux from brain tissue. We are looking at it in terms of powerline fields. We should have some results within the coming year.

Senator STEVENSON. Has similar research, namely on the behavioral effects of microwave radiation, been conducted and reported on in Eastern Europe or Russia?

Dr. RALL. Let me again ask Dr. McRee to answer that. We are part of a U.S./U.S.S.R. medical scientists exchange program and one of the program areas we are interested in is microwave nonionizing radiation research.

We are actively collaborating with the Soviet scientists on this particular area.

Dr. McREE. The Eastern European countries have reported numerous effects on low levels of microwave radiation. There has been an attempt to replicate in the United States—many of the experiments which have been done there.

At the levels that have been reported, in most cases they have not been able to be replicated.

Senator STEVENSON. You mean the results have not been the same or the experiments haven't been done?

Dr. McREE. It has been very difficult to replicate them exactly. You do not have enough information in their papers most of the time to determine exactly what they have done. The results have not been replicated because in many cases the experiment was impossible to be replicated.

However, as part of the U.S./U.S.S.R. agreement, we do have a duplicate project working at field levels of 500 microwatts which is considered by the Soviets to be a high level, which we consider to be a low level.

Using the same test system, behavioral tests, biochemical tests, in order to determine if the methodology is similar—if we do duplicate—we should replicate the effects.

Senator STEVENSON. OK.

Dr. RALL. I think this is the first attempt that I am aware of to sit down with the Eastern European scientists and say exactly what did you do, this is exactly what we are going to do, let's do it the same and see if it comes out the same on both sides of the Atlantic.

Senator STEVENSON. Is the California research being conducted by Ross Adey and Suzanne Bawin?

Dr. McREE. Yes, it is.

Senator STEVENSON. When will we get the results of the collaboration with the Soviets and the Eastern Europeans?

Is that an ongoing, indefinite process or is it going to produce a concrete plan of action?

Dr. MCREE. The cooperative program is a continuing thing with updating an reviewing every 2 years.

The duplication of the project which I am talking about should be completed in the next fiscal year, that is the program was agreed upon for a 2-year period beginning last October. It will be completed within fiscal year 1978.

Senator STEVENSON. Dr. Rall, you said that NIH is concerned with the need to determine the lowest level per dosage of ionizing radiation consistent with a required diagnostic or therapeutic need. You also noted that damage from ionizing radiation can result from cumulative doses given for a variety of purposes.

Other witnesses have testified that the average person's exposure from diagnostic and therapeutic radiation is increasing in the United States.

The first part of the question: Do you agree with that?

Dr. RALL. Yes.

Senator STEVENSON. Well, how seriously do you view this situation and what steps, if any, should be taken to limit the potential health hazards associated with this increasing cumulative exposure? What can you do? What can you do to protect the population?

Dr. RALL. Well, there are a lot of things we can do to assure that the population is exposed to the lowest amount of ionizing radiation.

As I indicated, NIH is trying to develop diagnostic procedures that either do not use ionizing radiation, which of course is the best, or use as low a dose of ionizing radiation as is consistent with interpretative images. This ought, in the long run, to decrease the radiation exposure.

The very delicate issue of when a physician decides to use diagnostic X-ray procedures, whether or not he should do that, is fraught with an enormous number of problems. I think we need to educate our physicians to use X-rays as sparingly as is consistent with good medical practice.

That is very difficult, but that will help cut down the radiation to the population.

Senator STEVENSON. We ought to require public education. I don't think most people are aware of how much they have been exposed to, even for medical purposes.

Dr. RALL. It really has to be both the physician and the public. The physician has to know and the public has to be able to question whether or not this X-ray is necessary.

Senator STEVENSON. I am going to ask the staff to ask the next questions.

Ms. NELSON. Can you comment on the potential correlation of pancreatic cancer and the exposure of Tacan radar operators to microwave radiation?

Yesterday the witness from the Navy stated that any potential correlation was anomalous. Are your epidemiological studies addressing this?

Dr. Rall. I simply think it is too early to say there is a correlation or there isn't. Maybe we ought to look more extensively before we make up our mind.

Dr. Miller, do you have a comment on that?

Dr. Miller. Yes. I think such observations can be considered hypotheses which have to be tested by studying people who are exposed to radar to see if they develop cancer of the pancreas or some other organ more often than usual. Or take people with pancreatic cancers and look back in their histories to see if they were exposed to radar.

Ms. Nelson. Have you planned such a study?

Dr. Miller. No.

Ms. Nelson. Do you know of anyone who does?

Dr. Miller. I do not.

Ms. Nelson. What is the probability of men of that age developing pancreatic cancer? I believe the Tacan operators were in their 30's.

Dr. Miller. I can't give you such a figure. When adult cancers occur early in life, one has an opportunity to determine if there is an environmental cause. This is what happened with respect to DES-induced cancer of the vagina. Neoplasm usually affects elderly women, but when induced by DES, occurs in young women. When such clusters occur, there is a chance to search for an environmental cause.

Dr. Rall. These sorts of observations are very important. In and of themselves they don't prove anything, but as Dr. Miller said, they give you a chance to now ask and answer the question, is there a relationship? It will take future studies to determine that. Statistically it is unlikely.

On the other hand, with just two patients, almost anything can happen. Those very rare occurrences do happen every once in a while.

Senator Stevenson. I have never gotten into a subject on which there has been so much disagreement and so much confessed lack of knowledge. Everything is either being studied or hasn't even started to be studied or is just beginning to be identified as a possible problem.

If you could start from scratch with a clean Federal slate, how would you organize the research and regulatory activities of the Federal Government with respect to radiation?

Dr. Rall. Well, let me just sort of give my personal opinion. I am a pluralist and not a monolithist, if I may make up that word.

The varying demands from an agency concerned about developing energy for the United States are so different from an agency interested in protecting the health of the worker that I see sense in having each one of them have an effective research program.

Clearly by the same token these programs must be strongly and effectively coordinated so each knows what the other is doing, and if and when they duplicate, it is clearly an intentional duplication as we are now trying to do with the Soviets, because the results seem different.

I am also personally convinced that one needs outside independent research organizations independent from either those who do the regulation or those who are promoting a project.

The independent research organizations are the ones that provide the new ideas, the new leads, who bring up the disturbing facts that cast doubt on old regulations. So I think what I am saying is the organization, although it looks messy on a paper full of boxes, may not be that bad.

The coordination in nonionizing radiation that came from the Office of Telecommunications Policy we felt was very useful and enhanced the effectiveness of the limited resources quite significantly.

Senator STEVENSON. OTP?

Dr. RALL. We thought it was very effective.

Senator STEVENSON. How did you find it effective?

Dr. RALL. In coordinating the most reasonably effective use of very limited resources.

I understand, however, from Sunday's Times that as an organization, it may not be around. I would certainly hope that the coordinative function would be retained. I see no reason why it couldn't.

Senator STEVENSON. That story concerned us, too. Is there too much centralization of research in ERDA on responsibility for ionizing radiation?

Dr. RALL. That is very difficult to answer. There are clear advantages in centralization in which you get larger opportunities for interaction.

There are also tendencies for centralized research efforts to become ingrown and not as imaginative as others.

Senator STEVENSON. Or as independent?

Dr. RALL. Yes. I really don't know that I can come up with a clear answer on that.

Senator STEVENSON. Are adequate resources available to NIH now for its research in this field including the nonionizing radiation program that you referred to?

Dr. RALL. We anticipate that there will be. Our permanent facility is under construction. We have designed a special, very large laboratory which can use the sort of complex equipment we need for this sort of research.

If the resources flow to allow us to use that building adequately by early 1980, we should have a much more adequate program than we have now.

Senator STEVENSON. Thank you very much, gentlemen.

Again, we may take the liberty of following up with some written questions.

Dr. RALL. Thank you very much.

[The statement follows:]

STATEMENT OF DAVID P. RALL, M.D., PH. D., DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES ON RADIATION HEALTH AND SAFETY

Mr. Chairman and members of the committee, we appreciate the opportunity to appear before you to discuss the activities of the National Institutes of Health in the fields of ionizing and non-ionizing radiation.

Accompanying me today are Dr. Robert W. Miller, Chief, Clinical Epidemiology Branch, National Cancer Institute; and Dr. Donald I. McRee, Research Physicist, National Institute of Environmental Health Sciences.

INTRODUCTION

The National Institutes of Health is the Nation's principle instrument for both the support and conduct of research in the biomedical sciences and I am convinced that there is no comparable endeavor anywhere in the world in terms either of intensity or diversity of effort. However, even for such a broadly based effort, there must be a continuing concern with the careful selection of research areas in which to work. Thus, when the Atomic Energy Commission (now ERDA) was created and, as part of its mandate, began to develop a strong program in biology and medicine relating to ionizing radiation, the leaders of the NIH made the decision to move into this area only when it was critical to a specific interest of an NIH Institute.

Let me add an historical note. Prior to World War II, the NCI had a strong radiation biology program. Dr. Egon Lorenz, one of the first members of the National Cancer Institute, was a leader in research on the carcinogenic effects of ionizing radiation. His studies pioneered efforts to understand the biological effects of long-term exposure of large numbers of experimental animals to low doses of environmental pollutants—specifically x-rays. The first clear demonstration that physicians occupationally exposed to x-rays had a higher incidence of cancer was by Henshaw and Hawkins of NCI in 1944. This group was joined in the mid-40's by Dr. Alexander Hollaender. Dr. Hollaender was detailed to the Manhattan Project at Oak Ridge and ultimately became in the early 1950's the first Director of the Biology Division of the Oak Ridge National Laboratory. Thus, NIH played a major role in initiating the AEC's biomedical research efforts.

This policy was reviewed and reaffirmed when the National Institute of Environmental Health Sciences was created in 1966. The level of funding for the Biology and Medicine Division of the AEC at that time was comparable to the budgets of a number of NIH Institutes. However, throughout this period the NIH has cooperated with ERDA and utilized the extraordinary resources of a number of the ERDA National Laboratories as places in which to support work of high NIH mission relevance.

Thus, with respect to ionizing radiation, NIH programs focus specifically on ionizing radiation as a factor in disease or therapy rather than as a research area to be addressed in its own right. This contrasts very sharply with the problem of the health effects of non-ionizing radiation. When the NIEHS was created, we reviewed the status of research in environmental factors and identified non-ionizing radiation as an area which was receiving inadequate research attention. Thus, we proposed to develop a program to study the biomedical effects of non-ionizing radiation in this area.

In 1976, the House Committee on Appropriations directed the NIEHS to undertake a study of research needs in environmental health. This study, undertaken with the participation of more than 80 scientists from government, industry, and educational institutions, was submitted to the Committee in connection with its review of the 1978 budget this Winter. Chapter 5 of the report addresses the issue of physical environmental factors and makes recommendations regarding research needs in this field including non-ionizing radiation. With the Committee's permission, I would like to submit that chapter for inclusion in the record at this point.

IONIZING RADIATION

Research Regarding Diagnosis or Clinical Use

A number of the NIH Institutes are conducting research on the use of ionizing radiation as a diagnostic or clinical tool. For example, the National Institute of Neurological and Communicative Disorders and Stroke has established that Computerized Axial Tomography (CAT) scanners are effective and when used appropriately and with restraint can provide a valuable diagnostic alternative to some other neurological diagnostic procedures which have greater risk associated with their use, such as carotid angiography, cerebral pneumograms, and, to some extent, the isotope brain scan.

The National Cancer Institute supports and conducts research concerning the use of therapy with ionizing radiation. The NCI is studying methods to reduce radiation exposure during diagnostic tests, and is investigating the possible replacements for ionizing radiation diagnostic methods for such problems as brain, breast, and lung tumors. The National Institute of General Medical Sciences supports a variety of research projects aimed at the development of new radiation detection and imaging systems, development of computerized methods of interpreting radiologic images, the development of new radio pharmaceuticals, as well as studies on the basic molecular mechanisms of cell damage by ionizing radiation.

Cooperative Relationships with other Research Organizations and Regulatory Agencies

The NIH has a variety of cooperative and liaison activities with the other research and regulatory agencies. These include ERDA, the Bureau of Radiological Health, and the National Science Foundation. The coordinating activities occur both at the policy and working scientist level. As an example, NCI cooperates closely with the Bureau of Radiological Health in its programs. NIH provides peer review of BRH grants. NIGMS staff maintain close liaison with appropriate program officials in ERDA, the Bureau of Radiological Health, and the National Science Foundation regarding overlap of research areas, joint support of conferences, and proposed large-scale human investigations of radiation effects.

Efforts to Establish Diagnostic and Treatment Dosage Levels

The primary objective of much of the research NIH conducts in the area of ionizing radiation is to determine the lowest level of radiation exposure which is consistent with the required diagnostic or therapeutic technique. Since damage from ionizing radiation can result from cumulative doses given for a variety of purposes, it is important that no single dose exceed the minimum level required to accomplish the desired purpose.

Studies to Determine Environmental and Human Health Effects

As indicated earlier, the broad area of environmental and human health ef-cooperates closely with the Bureau of Radiological Health in its program. NIH has deferred to that agency in this area. NCI and NIEHS are, however, conducting and supporting epidemiological studies to determine if groups of patients exposed to diagnostic or therapeutic radiation (for example, radiotherapy for ringworm of the scalp and radioactive iodine thyroid uptake studies) show long-term health effects. NCI and NIEHS supported the large-scale studies that defined the lung cancer risk for uranium miners.

NCI has provided support for important new programs at the Atomic Bomb Casualty Commission (Japanese atomic-bomb survivors).

NONIONIZING RADIATION

In contrast to ionizing radiation, NIH and particularly NIEHS is committed to develop research aimed at broad understanding of the health effects of microwaves.

Cooperative Relationships with other Research Organizations and Regulatory Agencies

The principal group for coordination in this area of activity is the Office of Telecommunications Policy (OTP), through its "Interagency Working Group on the Biological Effects of Non-Ionizing Radiation." This group brings together all concerned Federal agencies. The OTP publishes a complete listing of research projects supported by these organizations. In addition, through the NIEHS, the NIH is represented on ERDA's "Interagency Advisory Committee on Electric Fields Effects for High Voltage Lines." Included on this committee are NIEHS, EPA, Federal Power Commission, Federal Energy Administration, OTP, NSF, the Fish and Wildlife Commission, and the Department of Labor.

Research Regarding Diagnostic or Clinical Use

The NCI is exploring the use of microwaves as an adjunct to the treatment of tumors.

Studies to Determine Environmental and Human Health Effects

The NIEHS supports and conducts most of the NIH research in this area. However, due to limited laboratory space and resources, the Institute has only been able to expose small biological systems to a constant field of microwave irradiation. Because it is important to know the dose of the exposure in order to correlate the incident exposure to the absorbed energy, our scientists have developed systems with well-characterized microwave fields. A refinement of the IEHS exposure system is that the biological specimen is located inside environmental chambers which allow us to control the temperature and humidity while the biological specimens are being irradiated. This provides the opportunity to look at electromagnetic field effects separated from gross heating of the specimens.

In order to correlate any biological effect with absorbed microwave energy, it is important to accurately charatcerize the amount of energy that the biological system is exposed to. Thermocouples or metallic devices used to measure the enenrgy exposure perturb the fields being measured. NIEHS scientists have developed small thermistor probes, liquid crystal fiber optic probes, and infrared thermography which can accurately measure energy being deposited in biological systems, but which do not disturb the system.

In this work, we are using plain-wave far-field exposure systems using horn irradiators, wave-guide exposure systems for cellular studies and isolated nerve preparations, and variable frequency systems with capability between 1 and 10 gHz.

Other work we are involved in includes research on the effects of microwaves on teratology (birth defects), fertility and immunology. On exposing developing embryos to microwave radiation throughout the developmental period to 5mW/cm^2, no gross deformities were measured if the temperature was not allowed to rise above normal developmental levels. However, small but statistically significant effects on hemoglobin and white cells numbers were measured upon hematological examiantion. In addition, scientists are investigating basic interaction mechanisms and the effects of microwaves on neural response. NIEHS is in the process of building our permanent research facility. This contains specially designed laboratory space for our Biophysics Laboratory.

We anticipate that when this becomes available in early 1980, we shall significantly increase our inhouse efforts on the biological effects of non-ionizing radiation. Currently, we are expanding contract research, and, at the Universities of Washington and Utah, the Institute is sponsoring research aimed at determining the effects of long-term, low-level microwave exposure; at the University of California at Los Angeles, work with 60 cycle fields (similar to power line electric fields) ; and at the Jefferson Medical College, research aimed at determining the pre- and post-natal effects of microwave irradiation.

CONCLUSION

There can be little question as to the importance of research on the biological effects of both ionizing and non-ionizing radiation. In the area of non-ionizing radiation, the NIEHS will continue to support research on the health effects of microwaves. Much remains to be learned. In too many cases, we are able to identify and describe what effects radiation has on biological systems; yet do not understand why they occur or by what mechanism of action. This task still stands before us.

My associates and I will be happy to answer any questions you may have.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND THE ANSWERS THERETO

Question 1. Several witnesses before the committee have testified that average population exposure from diagnostic medical and dental X-rays is increasing in the United States. How seriously do you view this situation, and what steps might be taken to limit the potential health hazards associated with this increasing exposure? Does adequate regulatory authority exist today to control population exposure to unnecessary diagnostic X-rays?

Answer. Because the U.S. Food and Drug Administration has the regulatory responsibility, as well as the expertise, in this area, we believe it would be better qualified to answer these questions. We are aware, however, that the Bureau of Radiological Health devotes a majority of its resources to the diagnostic ionizing radiation problem.

Question 2. (a). Uncertainty still exists with respect to the validity of the linear hypothesis for estimating population risk from exposure to ionizing radiation. What is the current status of the scientific debate on this question?

Answer. Recently, the HEW Committee to Coordinate Toxicology and Related Programs (for which I serve as Chairman), approved the report (attached) of its Subcommittee on Estimation of Risks of Irreversible, Delayed Toxicity. This report contains the following conclusion concerning the linear model:

"For the purpose of estimating an upper limit of risk associated with a given dose on estimating an upper limit of risk associated with a given risk, assuming no other complication factors, the linear model for low dose extrapolation should be used for incidence data. This should be the case until improved mathematical models based on biological considerations are developed, or in specific instances where sufficient biological information is available to indicate the appropriateness of an alternative model. The development of such improved models should be encouraged."

The report also quoted the BEIR (Biological Effects of Ionizing Radiation) Commission report of 1972 on the somatic effects of ionizing radiation, which recommended:

"At this time, then, the linear hypothesis, which allows the mean tissue dose to be used as the appropriate measure of radiation exposure, provides the only workable approach to numerical estimation of the risk in a population. Further, since there is no means at present of determining the value of the dose-effect slope in the low-dose region of interest, use of linear extrapolation from data obtained at high dose rates may be justified on pragmatic grounds as a basis for risk estimation."

The BEIR Commission, under the direction of the National Research Council of the National Academy of Sciences, has again been reconvened and is in the process of updating its 1972 report.

(*b*) What is your personal opinion as to whether a radiation threshold exists below which no permanent biological damage is associated with radiation exposure?

Answer. I do not believe anyone can answer this question with precision. But in approaching this problem, one must first ask the question: "A threshold for whom?" The human population in the United States, the population we are trying to protect, is a very large, diverse, genetically heterogeneous population, exposed to a variety of carcinogens and other toxic agents. Genetic variability to carcinogenesis is well documented, and we are beginning to understand some of the causes of this variability.

It seems therefore, that instead of saying, "This is the threshold," we really need to say, "This is the threshold for this person or this part of the population." Thus, the question becomes: "Whose threshold and when?"

Further complicating this problem is the fact that rarely is man exposed to radiation alone. He is instead exposed to a whole series of mixtures and compounds all at the same time—all of which may have already put him over whatever threshold might exist for any individual compound or agent. Thus, while it may be possible to establish thresholds in highly controlled laboratory situations, the heterogeneity of the human population in combination with the diverse nature of its exposure makes the application of these thresholds to man almost impossible in practical terms.

Question 3(a). In your prepared comments you state that "ten years ago the area of non-ionizing radiation was identified as an area in which there was a dearth of knowledge and no focal point for the conduct of biological research." What is your view of the situation today?

Answer. Although U.S. research programs to determine and evaluate biological effects of non-ionizing radiation have as yet failed to generate a data base upon which quantitative and scientifically sound microwave radiation standards can be promulgated for the general population, a large amount of research has been carried out during the past ten years at lower power densities than those previously used. This has enabled us to uncover a lot of new needed information, some of which shows no biological effects, and some of which shows biological effects at power levels of 10 mW/cm^2 (milliwatts per square centimeter) and below. Much more work is yet needed to fully evaluate the mechanisms of interaction of microwaves with biological systems.

As in the past, no real focal point exists for the conduct of this research. NIEHS, EPA, NIOSH, BRH, Army, Navy, and Air Force all have ongoing efforts; and each of these agencies determines its own programs. There is no focal point for determining the direction of the total research effort. The Office of Telecommunications Policy has, in the past, performed an important coordination role in this area, but not a decision-making role. This Office, however, has now been dissolved.

(*b*) What are the greatest current research needs in this area?

Answer. The greatest research needs all revolve around the need for determining the effects of long-term, low-level microwave exposure. Specifically, the needs were well summarized by the NIEHS-established Second Task Force on Research Planning in Environmental Health Science which recommended the following:

"1. Epidemiologic and clinical investigations, with emphasis on behavioral, immunologic, and teratologic effects, should be undertaken in groups of workers and others exposed to both high and low power densities of microwave radiation. Special emphasis should be placed on potentially heat-sensitive populations, for example, some elderly people.

2. Chronic low-level studies of animals exposed to power densities approximating the present occupational exposure guide of 10 mW/cm^2 should be undertaken. Emphasis should be placed on possible sensitive test systems, such as the developing embryo, immune defense system, central as well as peripheral nervous system, chromosomes, and possible cumulative effects on the lens of the eye and male reproductive function.

3. Theoretical and experimental research is needed to determine the basic mechanisms of the effects of various radiofrequencies on molecular and cellular components and the loci of interaction as a function of power density and frequency. Biologic systems, such as the brain, heart, ear, and lymphocyte, and model studies, including anthropomorphic models, should be emphasized.

4. Support should be continued for surveys to systematically evaluate the frequencies and intensities of electromagnetic radiation in the environment. The results should be incorporated in the design of laboratory bioeffects studies, particularly chronic studies.

5. Development of exposure systems that yield absorbed power and development of non-perturbing temperature, physiologic, and field probes should be encouraged so that the actual energy absorption and effects can be measured at the point of biologic interest."

(c) Is there adequate coordination of efforts?

Answer. As I mentioned previously, the Office of Telecommunications Policy (OTP) had performed a coordination role in this area. Through establishing the "Interagency Working Group on Biological Effects of Non-Ionizing Radiation," it had brought together representatives of NIEHS, EPA, NIOSH, BRH, VA, ERDA, NASA, CIA, FCC, FAA, NSF, Transportation, Agriculture, Commerce, and Defense (Army, Navy, and Air Force) and had collected a list of all projects undertaken or funded by these agencies. From an information point of view, this effort had been extremely helpful and had provided adequate coordination in terms of letting each organization know what the others are doing. The OTP has now been dissolved. We believe this coordination function is needed and should be maintained at some locus at an appropriately high level in the Executive Branch.

(*d*) Is more funding needed?

Answer. The epidemiologic, clinical, and long-term low-level animal exposure studies needed in this area are expensive. If we were to undertake them, more funding would be needed. However. there is another shortage that must be addressed before we could undertake the necessary work. That is in number of teams of physical scientists and engineers with thorough training and experience in electromagnetic fields and biologists and medical specialists with equally complete backgrounds in the biologic systems under study.

At our own Institute, we currently have only one scientist working in the area of non-ionizing radiation. We are in the process of building a permanent facility which contains specially designed space for our Biophysics Laboratory. When this becomes available in 1980, we hope to be able to significantly increase our inhouse efforts on the biological effects of nonionizing radiation.

(e) Do you perceive real health problems from our lack of knowledge, such as in the regulation of microwave ovens?

Answer. There is presently much public, as well as governmental and scientific, concern for the safety of microwave devices already in use and the possible environmental impact of planned microwave sources in this country. This concern is due in part to the conflicting basis of the U.S. and Soviet exposure guides and in part to the recent reports of biologic effects at power levels less than 10 mW/cm^2.

The United States, France, and West Germany have generally accepted a power density exposure level of 10 mW/cm^2, but the Soviet Union and Poland specify a permissible level of 0.01 mW/cm^2. The fact that there is a factor of 1000 between the accepted U.S. standard and the Eastern European standard results from the different basis used for determining biological effects. The U.S. accepted standard is based primarily on the cooling capability of the body (thus, a thermal effect), whereas the U.S.S.R. and Poland standards are based primarily upon the interaction of microwave fields with the brain and central nervous systems (a neurological or behavioral effect). Before these disagreements in the standards for safe levels of microwave exposures can be resolved, more accurate, well defined experiments must be conducted. At the present time, I do not believe anyone knows what low-level exposure over a five year period will do in terms of biological effects. Nevertheless, if the Soviet research is correct, it indicates there would be some biological effects (primarily neurological effects) resulting from such exposure. So far, it has been difficult for American scientists to reproduce the foreign clinical and laboratory studies because of lack of experimental details in their publications. But our lack of knowledge is such that we cannot rule out the possibility that there is a potential for real health problems. Thus, we must implement the needed research in order to clarify the conflicting data and the resulting conclusions so that a quantitative microwave exposure standard can be established.

Question 4. On page 7 of your prepared comments you referred to research into "the effects of microwaves on teratology, fertility, and immunology." Could you please summarize any results of this research to date, as well as the results of your other studies on basic interaction mechanisms and the effects of microwaves on neutral response?

Answer. In studies to evaluate whether exposure to microwaves during embryonic development has an effect on the developmental process and function of the organism after maturity, we found that exposure of fertilized Japanese quail eggs to a power density of 5mW/cm^2 for the first 12 days of development produces no gross deformtiies or changes in hatchability. Five weeks after hatching, the exposed and unexposed juvenile quail have the same ability to produce antibodies in response to a challenge by foreign cell types—indicating no change in immunological function at that time. At maturity, exposed males—when mated with either control or exposed females—exhibit a ten percent decrease in fertility. Preliminary tests show that at 22 weeks of age female exposed quail exhibit a significant increase in spleen and bursa size and a decrease in liver weight. Experiments will continue to determine why fertility is decreased in exposed males and to evaluate the effects of microwave radiation on body organs. An immunological evaluation will also be made of 22-week-old quail.

Our work on basic interaction mechanisms is concerned with determining how 2450 MHz microwave radiation interacts with biological material at the cellular and macromolecular level. Several studies in the past have reported effects at the cellular level resulting from exposure to 2450 MHz microwave radiation. We undertook similar studies, except we tried to carefully control the temperature, humidity, and other growth conditions in order to eliminate any effects not intrinsically caused by the microwave radiation. Our results showed very few differences between exposed and control samples that could not be explained by the thermal heating of the microwave radiation.

In other work we are attempting to determine the effects of microwave radiation on neurological response. Isolated neurons, such as the sciatic nerves of frogs, are exposed to continuous wave, pulsed, and modulated microwave radiation in the power density range of 1–10 mW/cm^2. Initial experiments show that the exposed frog sciatic nerve, which is simultaneously stimulated to produce an action potential, fatigues at a much faster rate than the control nerve when exposed at 2450 MHz continuous wave microwave radiation. We are now decreasing the power to obtain a threshold for the effect; and we will continue to investigate the mechanism of interaction of the microwaves with the neural specimens.

Question 5.a. What is the current status of the contract research being done at the Universities of Washington and Utah on the effects of long-term, low-level microwave exposure, at the University of California at Los Angeles on sixty cycle fields, and the research at Jefferson on pre- and post-natal effects of irradiation. When were these begun and when will they be completed?

Answer. Work done under contract at the Universities of Washington and Utah is aimed at determining the effects of long-term, low-level microwave exposure on behavior, neurochemistry, and electroencephalograms. Under the contract at Washington (initiated on June 20, 1976 and to be completed on December 20, 1978,) pregnant rats were exposed to 918 MHz continuous wave microwaves at an incident power density of 5mM/cm^2. The exposure was for 20 hours per day for the first 20 days of gestation. No chages in viable offspring or stillborns were observed. Trends toward accelerated development and eye opening in the exposed groups were noted. Growth rates are now being measured. At 90 days of age, acquisition and extinction of conditioned shuttlebox avoidance response will be measured. In addition, exposure of adult rats for 8 hours per day, 7 days a week are now in progress. These exposures will be at both 918 and 2450 MHz and 5mW/cm^2 for a 16 week period. The rats' biochemistry, behavior, and EEGs will be evaluated.

Under the contract at the University of Utah (begun on June 28, 1976 and to be completed on June 27, 1978), methodology and equipment for determining the effects of long-term, low-level exposure to 915 and 2450 MHz microwave radiation on the central nervous system and behavior have been developed. During the next year, the exposure of rats to 915 and 2450 MHz microwave radiation will be carried out. These animals will be monitored for an eight week period after completion of exposure; and biological endpoints relating to biochemistry, behavior, and electroencephalograms will be evaluated.

Under the contract at the University of California at Los Angeles (begun on October 1, 1975 and to be completed on September 30, 1978), environmental field conditions similar to those found in the vicinity of high voltage transmission lines are being simulated; and the effects of these fields on the biological rhythms in rats are being evaluated. Brain tissue, as well as whole-animal, exposures are being performed. So far, an increase in calcium efflux from brain tissue has been measured using low-field intensities. The work will continue to determine if there are other changes in the neurochemistry of brain tissues of cats exposed to these microwave 60-cycle electric fields.

Work is continuing at Thomas Jefferson University to further develop techniques and instrumentation for determining exposure and dosimetric parameters, and for determining the low dose effects of chronic prenatal microwave irradiation on embryonic and fetal development, postnatal development, reproduction capacity, and on the nervous system. An important objective in these studies is to devise methods and models that will enable scientists to discriminate between heat effects as opposed to other types of effects. The grant which supports this work was awarded on June 23, 1975 and terminates on May 31, 1978.

(*b*) Do you support the idea of an epidemiological study to investigate the possibility of the alleged relationship between microwave exposure and pancreatic cancer?

Answer. I believe epidemiological studies are needed to investigate many biological endpoints. However, the problem of eliminating other causal factors has in most cases been impossible because it is difficult to find populations with the same living conditions except for microwave exposure. Thus, I am not convinced an epidemiological study on this topic would be fruitful at this time.

Senator STEVENSON. Thank you.

The committee will recess until tomorrow morning at 10.

[Whereupon, at 1:33 p.m., the hearing was adjourned, to reconvene at 10 a.m. Wednesday, June 29, 1977.]

RADIATION HEALTH AND SAFETY

WEDNESDAY, JUNE 29, 1977

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, D.C.

The subcommittees met at 10:07 a.m. in room 5110 of the Dirksen Senate Office Building, Hon. Adlai Stevenson presiding.

Senator STEVENSON. This is the last day in this series of oversight hearings to evaluate the adequacy of the Federal Government's efforts to protect citizens from the effects of ionizing and nonionizing radiation. It is evident from the record to date that many questions remain unanswered, including whether research on nonionizing radiation is adequate and is responsive to the public health needs; should the licensing of X-ray technicians be made mandatory under Federal law; is coordination between Federal agencies and State programs adequate; are there new areas or technologies such as combustion and conversion of coal that need to be studied to determine if serious radiation problems will exist in the future.

It is hoped today's witnesses will be able to help answer these questions.

We will hear from the Office of Telecommunications Policy, the National Academy of Sciences, the Conference of Radiation Control Program Directors, and the Association of State Radiologic Technologists. Our first witness is Dr. William Thaler, Acting Director, Office of Telecommunications Policy.

STATEMENT OR DR. WILLIAM J. THALER, ACTING DIRECTOR, OFFICE OF TELECOMMUNICATIONS POLICY, EXECUTIVE OFFICE OF THE PRESIDENT; ACCOMPANIED BY JANET HEALER

Dr. THALER. Good morning, Mr. Chairman.

Senator STEVENSON. Good morning.

You are welcome to summarize your statement if you prefer, in which case it will be put in the record.

Dr. THALER. I have with me today Ms. Janet Healer from the Frequency Management Group in my office responsible for the coordination of our work in this area.

OTP's involvement in electromagnetic radiation (EMR) research is an integral part of our responsibility to coordinate telecommunications activities and associated research within the Federal Government. Insuring that the use of nonionizing electromagnetic energy does not harm man or his environment is a major task within that responsibility.

The Federal program, coordinated by OTP, is designed to develop a sound scientific understanding of the interaction of EMR energy with living systems. This will serve as a basis for evaluating possible biological risks from given levels and conditions of EMR and for developing appropriate controls which may be warranted to insure safe and effective use of the spectrum. Five years ago OTP recommended and undertook the coordination of a cooperative multiagency program to investigate biological effects of this energy.

Our efforts involve radio frequency radiation. Like visible light and infrared, these radio waves are nonionizing radiation. Regrettably, the use of the term "radiation" often elicits confusion between this energy and ionizing radiation such as X-rays and nuclear radiation. There are important differences which determine how these different radiations interact with the body and their potential for causing harm. For example, a quantum, or individual bundle, of radiofrequency energy contains far less—approximately a million times less—energy than a quantum of ionizing radiation which can break molecular bonds, produce ionization, and do significant biological damage.

The use of radiofrequency energy has been growing rapidly. Today the radio spectrum is a widely used and an integral part of modern society. It supports such telecommunications services as radio and TV broadcasting, citizen band radio, radars, air and marine navigation and safety systems, and emergency medical services. The spectrum is also used in industrial processing, medical equipment, and consumer products.

We have been working with nonionizing electromagnetic radiation since the days of Hertz in 1890. The first two decades of the 1900's saw the commercial and military uses of this radiation become a reality. The development of more powerful and diverse emitters using a wide range of frequencies during World War II stimulated further advances in this technology and its applications—thus increasing the potential for exposure to EMR. Yet, by the mid-1960's, our knowledge of the biomedical activity of nonionizing radiation was still very limited.

The first major U.S. effort to increase that knowledge between 1957 and 1961 was a Tri-Service program supported by the Department of Defense. It had been known for some time that radiofrequency radiation at sufficiently high levels could cause harmful effects through energy absorption and heating. Studies were conducted in the Tri-Service program which demonstrated some of these harmful effects at power density levels around and above 100 milliwatts per square centimeter. Effects of thermal stress on the body's heat dissipating capability were also studied. These studies contributed to the acceptance of 10 milliwatts per square centimeter, based primarily on thermal considerations, as a permissible exposure limit below which harmful effects would not be expected to occur. This level has since become the basis for present standards in the United States and most Western countries.

Following the Tri-Service program, nonioning electromagnetic radiation research came to a near standstill in the United States, but throughout the 1960's there was an increasing awareness of apparent differences between the United States and the Soviet concepts of the levels at which hazards from nonionizing radiation occurred. U.S. literature showed harmful effects from short exposures a high milliwatt per centimeter levels, while the Eastern literature claimed harmful effects in the low milliwatt per square centimeter and in some cases even the microwatt per square centimeter levels.

Also, the Eastern countries established standards with maximum permissible exposures considerably lower than ours.

Their observations included the effects on the nervous system and behavior, differenes between various frequencies and waveforms, and long-term exposure effects at levels below those associated with measurable heating.

Toward the end of the 1960's there was a convergence of attention and concern by the Government, the scientific community, professional groups, and industry which led to the ANSI standard in 1966 and to the passage of Public Law 90–602 which established the electromagnetic product radiation control program.

In 1967, the Office of Telecommunications Management, OTP's predecessor, initiated efforts to provide a central focus and review process in this area. The first step taken was the establishment of the Electromagnetic Radiation Management Advisory Council, called ERMAC. The ERMAC conducted an extensive review of scientific knowledge, research requirements, the status of research programs, and funding levels. They recommended guidelines, initial research priorities, and increased funding for a coordinated program of investigation among responsible Federal departments and agencies.

The ERMAC is now reviewing its first 5-year plan in light of more recent research and is preparing updated guidelines for future efforts. One of ERMAC's major contributions was the recommendation that OTP, as an independent and impartial entity in the Executive Office, serve as an overview and coordinating body with assistance from the Council. Our role includes emphasizing the importance of this research among other competing agency priorities and attempting to insure that the overall program goals are being adequately addressed.

The basic program objectives continue to be, first, to determine what biological effects radio frequency radiations cause under different conditions of exposure; second, to determine the biological significance of any effect and evaluate the risk in a realistic exposure environment; third, to establish a sound scientific basis for any remedial or control measures which appear needed; and fourth, to insure that U.S. safety criteria provide an adequate margin of safety.

Where do we stand today?

Let me emphasize that the research program to date has identified no positive evidence of harmful effects to man at the levels of exposure normally encountered by the general population.

No crisis has been found to exist. No cause for public alarm has been identified. We must, however, be absolutely certain that nothing has been overlooked and we recommend continued and accelerated pursuit of the necessary research.

Mr. Chairman, I am pleased to report there have been some real accomplishments since this committee's hearings in 1973. First, we have succeeded in creating an effective Executive Office focal point and forum for Government activities related to the biological effects of radiofrequency radiation.

Second, each agency has designated representatives who meet with ERMAC and serve as members of an interdepartmental working group to continually monitor and improve the overall efforts.

Third, relevant research has been identified at the work unit level and organized to facilitate analysis and coordination of research efforts.

Fourth, there has been an increase in exposure facilities available to conduct research over the wide range of frequencies and waveforms of interest.

Fifth, substantial progress has been made in the actual conduct of the research; better techniques and instrumentation have improved our ability to associate biological responses with exposures.

Previous witnesses have elaborated on the specific research and its results. I will not repeat the details. Our office has produced an annual report for the last 4 years which goes into some detail with respect to the specific research and its results. We can certainly make copies of those available to the committee if you don't already have them.

Senator STEVENSON. I believe we already have them.

Dr. THALER. Fine. It is important to note that nonionizing electromagnetic radiation research is a difficult field to work in. It is difficult to quantify how much energy is actually absorbed from the incident radiation due to the complex geometries, the layers of differing electrical properties, the frequency dependence of penetrations, possible resonance effects and so forth.

In the course of the research, biological effects have been observed and reported in experiments with small laboratory animals at levels around and even below 10 milliwatts per square centimeter. These effects include changes in learned behavior or task performance, radiation perception, and apparent alterations in electrophysiological measurements of nervous system activity.

These do not necessarily imply hazards to man for many reasons. For example, differences in size and mass between humans and laboratory animals with respect to frequency and power density and the nature of an effect are among many factors which need to be taken into consideration in assessing or interpreting this research.

Nevertheless, systematic study must continue to be vigorously carried out to determine under what conditions biological effects occur and what their significance is to man. In assessing the impact of this radiation on man, we must first develop a realistic picture of actual exposure environments and the populations involved. You have had testimony from the Department of Defense and from the Environmental Protection Agency on this point.

While the actual measured data is still somewhat limited as the program is continuing, it appears that radiation levels in most environments normally encountered by the general public do not exceed 1 microwatt per square centimeter, which is 10,000 times less than the present occupational safety standard of 10 milliwatts per square centimeter.

Our experience over the past few years has also made it possible for us to identify some of the problems and deficiencies in the program. Let me illustrate some of these problems.

First, electromagnetic radiation research has to compete for resources within each agency against many other programs, some with more urgent priority within the agency's mission.

Second, research requiring relatively large and stable funding, such as experiments with long-term chronic exposures and large epidemiological studies, is beyond the particular resources of any individual agency.

Third, certain types of research, basic research, for example, are not being funded at a high enough level because of the mission orientation of some of the agencies.

Another complicating factor is public apprehension over the question of the safety of microwaves and toher nonionizing electromagnetic radiation. Undertaking a research program in itself can imply that a hazard is either known or suspected.

As the research program begins to produce results, its visibility increases which leads to more publicity in the public press.

Unfortunately, because of the complexity of the subject, the information in the press is sometimes limited, out of context, and difficult to interpret.

The apparent differences in Eastern and Western research and safety standards adds to the confusion.

In summary then, research to date has not demonstrated that any hazard to the general population exists. However, many questions remain unanswered. Resolutions to these questions and experience gained make it possible to identify outstanding research needs and priorities.

These are: First, experiments to investigate effects of long-term relatively low-level exposure; second, studies of people exposed in specific occupations or experimental circumstances; third, increase investment in basic research, including investigations of mechanisms of biological interaction; and fourth, additional development and refinement of techniques for computing comparable doses of radiation, for measuring internal energy fields and energy distribution, and for interpreting laboratory findings to man.

That completes my summary, Mr. Chairman.

Senator STEVENSON. You have spoken interchangeably of EMR and also RF.

As I understand it, EMR can include RF, also microwaves. Is that right?

Dr. THALER. Yes, sir.

Electromagnetic radiation covers the entire spectrum from zero frequency on out through the gamma rays and X-rays. It includes both ionizing and nonionizing radiations.

The RF part of the spectrum is a specific part of the spectrum which lies between a few cycles per second—hertz—well, the radiofrequency is higher, but in general, it is a frequency regime that cuts off just below the visible light. Radiofrequency spectrum lies between—radio, about 3 megahertz up to something on the order of 300 gigahertz. For our purposes we include frequencies between zero hertz and 300 gigahertz.

Senator STEVENSON. It does not include microwaves; is that right?

Dr. THALER. It does include microwaves.

Senator STEVENSON. That's what I want to make clear. Your references to RF, we are talking about microwaves?

Dr. THALER. Yes. Microwaves are a part of the radiofrequency spectrum. They are the shorter or higher frequency radio waves.

Senator STEVENSON. The exposure of the average person to radiation from this source has probably been increasing, hasn't it, in recent years?

Dr. THALER. Yes, Mr. Chairman.

I think due to the increased usage of radiofrequency sources in broadcasting and radars and such. The proliferation of equipment certainly means on the average a general rising level.

Senator STEVENSON. From the growing use of microwaves?

Dr. THALER. Yes, indeed.

Senator STEVENSON. That is a trend which is likely to continue in the future, is it not?

Dr. THALER. I certainly would expect so.

Senator STEVENSON. Could you generalize about that trend? Is it straight up? Up slightly? Or is the exposure radiation from these sources likely to go up—at what—roughly at the same rate as the recent past in the future?

Dr. THALER. Mr. Chairman, I think there will be a continuing increase in the use of these radiations in the radiofrequency range. It is difficult to predict what the far-term future holds, because many of the new technological advances such as coaxial cable and fiber-optics may take many of these sources off the air and restrict them in transmission over these guided media, in which case they will no longer be radiating into the atmosphere.

It is a fairly complicated question.

Yes; I would expect there would be a continuing increase, but I don't think it is particularly a steep-sloped increase.

Senator STEVENSON. After completion of the Tri-Service program, why did research come to a standstill?

Dr. THALER. I am under the impression, Mr. Chairman, that the major hazard that was envisioned at that time was due to the local heating by absorption of microwave energy at levels of 100 milliwatts per square centimeter.

Once that problem appeared to have been adequately addressed by the Tri-Service program, and a safety standard of 10 milliwatts per square centimeter had been reached, there was not an extensive body of literature available indicating any long-term effects of a more subtle nature at lower exposure levels.

It was felt at that time that the pressing problem had been solved, and except for some continuing research by people who were interested in the field, there was no concerted effort to try and extend the work down to lower exposure levels and more subtle effects.

Senator STEVENSON. Do you have any indication about the President's plans for OTP and the proposed reorganization of his office? If OTP is removed from the Executive Office of the President, how will its coordinating role for Federal research on the nonionizing radiation continue?

The third part of that question is how should it continue? How should it be organized?

Dr. THALER. Mr. Chairman, as you know, most of the Executive Office of the President are as much in the dark as the general public as to exactly what the reorganization plan will look like.

In my discussions with the reorganization study teams, I am convinced that they do, in fact, realize the importance of maintaining the major policymaking functions in the telecommunications area somewhere at the level of the Executive Office of the President.

This particular area is a matter of national concern. It cuts across all governmental agency lines. Every Government agency uses telecommunications equipment or services.

I have reason to suspect this subject area will remain at the Executive Office of the President in terms of the direction of the program and that the excellent coordination effort that OTP has effected in the past will not be lost in the transfer to whatever new structure the President decides to initiate in the Executive Office.

Senator STEVENSON. Would it be strengthened if combined with an agency at the same level with a coordinating responsibility for regulation and research on ionizing radiation?

Dr. THALER. Mr. Chairman, I would not consider that to be a particularly helpful move. The technical problems involved in treating nonionizing electromagnetic radiation, biological effects, are completely different than the problems involved in looking at the effects of ionizing radiation.

The mechanisms are different. The range of the spectrum is different. The technological skills required to investigate this area are different.

My feeling is that the subject is important enough in its own right not to get married in with an effort that has been going on for 30 years in ionizing radiation, which has developed a vast body of information and expertise.

My fear is it might become a second-class citizen in such an environment. I think it deserves a more forceful continuation of our existing programs.

Senator STEVENSON. You indicated that the funds to which you have access are not adequate.

What would be adequate?

Dr. THALER. Mr. Chairman, trying to estimate funds is a difficult problem.

If you approach it from the truly scientific basis and say what kind of programs would you like to support, you can come up with an estimate that, in my opinion, would be something on the order of two or three times the funds that are now expended in this area.

Senator STEVENSON. You indicated $9 million?

Dr. THALER. The present level of expenditure is $9 million.

The problem, of course, is that all the funds that the taxpayers put in have to be allocated across the board on the basis of priorities.

I think one of the major tests that OTP sees for itself is to try and keep this interest we have generated in the program at least at the level it is now, and hopefully encourage agencies who make their funding estimates to attempt to get OMB to approve additional funding. Hopefully we can bring this matter under closer scrutiny by the White House staff to try to convince the President to believe that this is a matter that requires additional funding and can still be done and balanced off within his overall budget priorities.

That's our basic problem.

Senator STEVENSON. The $9 million goes to the various agencies?

Dr. THALER. Yes.

Our sole function is to coordinate and integrate research programs and try to encourage the agencies to put the funding level into their budgets that the coordination group determines is the proper level for research.

Senator STEVENSON. How much authority do you have to actually allocate the $9 million?

Dr. THALER. We do not have any authority to program or allocate funds in this area. We can recommend to the agenices through our ERMAC processes what we think their funding level should be in order to satisfy the goals and objectives that ERMAC and the interdepartmental working group have established.

They then have to weigh our recommendations against all the competing priorities they have, the constraints they have from the budget generation process and come up with an optimum amount—an adequate amount to fulfill our objectives.

Senator STEVENSON. Could you recommend, in addition to increased funding, increased authority over the allocation of those funds in OTP or its successor? Should that coordinating agency have more than just a coordinating influence on these agencies?

If so, what should it be?

Dr. THALER. Mr. Chairman, that would be helpful in the sense it might allow us to generate more funds to get into the battle.

Actually, the present process, which has been, I think, a very fruitful, cooperative effort between all of the agencies and OTP as the coordinator, is an endeavor that I would not like to see caught up in the tensions involved in their feeling that we were imposing our will on their efforts.

Everyone has done, I think, the best that they could under the budget constraints to come up with the funds.

I really think our coordination efforts have been reasonably successful. My hope is that I can raise this concern at the Presidential level to the point where the agencies may be permitted to make decisions on the priorities for their fundings that will enhance support in this area.

Senator STEVENSON. Senator Schmitt?

Senator SCHMITT. Thank you, Mr. Chairman. I apologize to you, sir, for missing your testimony. I quickly scanned portions of it.

In the work of your group, have you examined and compiled the biomedical research that is going on in the country on the effect of various levels of nonionizing radiation on plant growth, animal response and so on?

Could you summarize the general areas of research and tell us whether there are any significant effects being noted?

Dr. THALER. I would like to ask Ms. Healer to respond to that question.

Ms. HEALER. Our office does not conduct research directly, but we do—with our advisory council and in the interagency forum—continually review the results of research as they are forthcoming.

Senator SCHMITT. As published, or as results actually are obtained?

Ms. HEALER. Both. We hold seminars, for example, in selected research areas. For example, on research into nervous system and behavioral effects, measurements of environmental levels, and so forth.

In addition, we also review research on an agency basis. We do continually try to maintain reviews of research, as it is being conducted.

Senator SCHMITT. Let's take microwaves, for example. What is the status of animal response to various levels of microwave radiation?

Ms. HEALER. That is a very broad question.

Senator SCHMITT. I realize that. Can you give the committee any insight?

Ms. HEALER. This research is conducted to look for the whole range of possible human or living system response to radiofrequency—including microwave—radiation.

A number of different end points are being looked at.

Some of these are derived from the published Soviet literature and the kinds of effects they report.

Therefore, there is a good deal of research investigating potential nervous system and behavioral responses, in a variety of animals and at a variety of frequencies. We had at the outset recommended some frequency and biological priorities. I think the research efforts follows those guidelines.

Other biological parameters are also being investigated. We have seen changes in some of these biological parameters. However, it is still early to say what the significance of these changes are for the animal in some cases and certainly for man.

Dr. Thaler mentioned some of these effects in his testimony. For example, we have seen that animals seem to be able to perceive the presence of microwaves or radio. These experiments involve a divided box—referred to as a shuttle box. One side is illuminated with microwaves and the other is shielded so that it is not. The animal is free to spend its time on either side of the chamber.

It has been observed that animals tend to spend more of their time in the shielded portion of the chamber, rather than the side where the microwaves are. It is difficult to determine at this stage the significance of this finding for man. Such observations are being investigated further.

Senator SCHMITT. Your recommendations are made to the National Science Foundation and other agencies which are funding various types of research?

Ms. HEALER. I am sorry. I didn't hear the question.

Senator SCHMITT. You said you made recommendations on certain radiofrequency areas which should be investigated. Are those recommendations made to the other Government agencies to guide their research programs?

Ms. HEALER. Yes. They are recommendations for the overall Federal Government program.

Senator SCHMITT. Are there any recent summaries of research results in biological responses which would be useful to submit to the committee for the record?

Ms. HEALER. Yes—I think some have been submitted already to the committee. There are many such reviews. Our office summarizes program activities annually. This is an overview kind of summary. Our reports also contain reference to specific ongoing research and to scientific publications to try to give feeling for what kinds of research different agencies are doing.

A number of individuals and groups, such as the World Health Organization and ANSI (a widely recognized professional body), among others, have also published reviews and research recommendations.

Senator SCHMITT. Does the committee have an up-to-date summary of the most recent measurements?

Ms. HEALER. Yes.

Senator SCHMITT. You mentioned the Soviet research efforts in this area. Generally, they have had somewhat different safety standards relative, for example, to microwave radiation. Would you care to comment on that difference and the reason for it?

Ms. HEALER. I wish I could tell you the specific reasons for it. I can say this: first of all, I think it is important to remember that all safety standards—in any country—are not set at the threshold where harmful effects occur.

In fact, in their design, all safety standards are intended to incorporate a margin of safety below the lowest level at which it is felt effects might occur.

They are also based upon the best available information at any given time. As such, they are manmade criteria and should not be blindly worshipped. They should always be subject to review as new knowledge becomes available.

This, in fact, is happening not just in this country, but also in the Soviet Union at the present time.

We don't know the precise reasons or the basis for the Soviet standards, but there are indications that to some extent the differences may, in part, be due to differences in interpretation of effects and what one considers a hazard. All effects, of course, are not necessarily hazards.

There may also be differences in approach in the development of safety standards.

Until recently, there has been very little contact between East and West in this area. There hasn't been an opportunity to try to resolve these differences.

Recently, under one of the U.S.–U.S.S.R. collaborative agreements, as mentioned by Dr. Rall of NIEHS, there has been developed a collaborative research program in the microwave area.

It is a small effort at this stage, but we are very hopeful that this exchange will be helpful. It does include a rather exciting aspect, I think. That is, an opportunity to conduct a duplicative experiment which we are going to try to make as precisely alike as possible.

We hope this will give us an opportunity to get a better understanding as to the basis for some of these differences.

Senator SCHMITT. In the microwave area, they basically set a lower standard or a lower threshold?

Ms. HEALER. Yes; they have. It is an apparent factor of 1,000 lower.

Senator SCHMITT. Has your office been involved at all in the discussions between ERDA and NASA concerning satellite power systems and the use of microwaves to transmit large amounts of power from space to Earth?

Ms. HEALER. We have followed the development of this concept. OTP, in fact, has followed it for reasons of spectrum support. We have been briefed in the ERMAC and also in the scientific working group on proposed systems and associated research.

I believe the biological considerations of what kinds of research might need to be done to support that activity are still in the planning stages.

I am not personally certain where that responsibility finally lies. However, we have heard from both NASA and ERDA on that subject.

Senator SCHMITT. Do you have any plans to get further involved in this discussion? The generation of power in space is one of the options for the early part of the next century. It is one I think the administration should be paying some attention to, with the emphasis on the use of solar energy for conserving energy resources.

Dr. THALER. We certainly will. Our responsibility in the telecommunications area is very broad. We certainly would consider that. We would have to allocate the frequency to begin with, because it would be a Government activity.

At least if a private corporation does it, we would have to advise the FCC. We certainly will get more and more involved in considerations of that whole area.

Senator SCHMITT. Would you get involved in considerations of safeguards to prevent any misapplication of large amounts of microwave energy from space?

Dr. THALER. I think, basically, our role in that area would be to cooperate with those agencies that have the regular responsibilities for safety, the EPA, the Bureau of Radiological Health, and so on.

We certainly do cooperate with them and make our comments on these specific areas under question to try to reach an accommodation that will be supportive of our efforts to discharge our responsibilities in this area and will be in line with the present up-to-date state of the art in trying to predict potential risks and hazards.

Senator SCHMITT. Do you have any feeling at the present time as to what is an acceptable level for broad microwave transmission at the Earth's surface? Or do you feel it is too early to say whether any level will be acceptable?

Dr. THALER. Well, Mr. Schmitt, as I stated in my testimony, there is no evidence that at power levels to which the general population is now exposed there is any risk or hazard. There just simply is no evidence.

I have looked at the Soviet literature in this area.

I find it very confusing. If I may say so, as a physicist, it is an interdisciplinary area where much of the initial work has been done largely by the biologists.

I think you are a physicist, too, aren't you?

Senator SCHMITT. I am a geologist. I have some background in this area. The same confusion exists in geology.

Dr. THALER. The kinds of parameters that, as a physicist, I would look for in terms of a specific statement of the frequencies, specific statement of the power level, what kinds of instrumentation were used to measure these levels, and so on, is so fuzzy.

That's been one of the reasons why it has been almost impossible to duplicate the Russian experiments in this country.

Senator SCHMITT. There is a very strong tendency to publish results and not technique?

Dr. THALER. Right. That complicates the situation. This whole area of low-level long-term exposure is an area that is exceedingly difficult in a multidisciplinary field like that. We really do need to get more work between the various disciplines involved in a cooperative effort in this area.

We have to get the engineers, the physicists, the medical people to talk the same language.

I have done research in biophysics. The hardest part is to get the biologists to understand what the physicists' terms mean and what kinds of standards we require in our experimentation and vice versa.

Janet says that maybe one of the biggest accomplishments we have made in our program of coordination is actually getting these disparate disciplines more closely involved in a cooperative effort.

Senator SCHMITT. One final question: Have any of your activities taken you into the area of high intensity magnetic fields?

Ms. HEALER. Not per se. We are interested, of course, in the electric and the magnetic components of the electromagnetic field in terms of the possible differences in their biological effects. Not high intensity magnetic fields per se as you mean.

Dr. THALER. I must say one of my faculty at the university from which I came is involved in this area using superconductive magnets. He has noticed some very interesting biological effects of these intense magnetic fields. Of course, a person would never normally be exposed to such a field.

Senator SCHMITT. Not yet anyway.

Dr. THALER. Not yet. In the future, who knows? It may be an area of considerable interest.

Senator SCHMITT. There are a number of futuristic energy conversion systems which could potentially use intense magnetic fields. Again, it is something that I hope you will not ignore completely.

Dr. THALER. We will be there.

Senator SCHMITT. In recommending some level of research in the country, through Government agencies, it is important.

Dr THALER. Yes; indeed.

Senator SCHMITT. Magnetohydrodynamics, and a number of other concepts, including fusion, will require those intense fields. Hopefully they will be focused fields. Nevertheless, people working with them will be exposed to higher levels than normal. I think there is fairly persuasive biological evidence that magnetic fields do have some influence on how life develops.

Dr. THALER. Yes indeed.

Senator SCHMITT. Thank you, Mr. Chairman.

Senator STEVENSON. One more question.

Do you think that enough research has been conducted now to justify funding of a major study on the effects of nonionizing radiation, a study similar to the National Academy of Science's BEIR report?

Dr. THALER. Mr. Chairman, my feeling is that at the moment we are nowhere near the level of information that would make a BEIR type study reasonable. If you look at the expenditures over the last 30 years in the field of ionizing radiation, the body of literature that has been generated, it is just of staggering proportions. The amount of work, literature that we have so far managed to generate is relatively small compared to that effort.

I do feel, however, that a study by an independent body like the National Academy of Sciences could be very useful in focusing on two areas. First of all, a general kind of independent review of what has been done, but more important, as Mr. Schmitt mentioned, I am also concerned about what the future holds with new techniques, new equipments coming to the fore.

I don't think this has been done yet. Somebody ought to look at present technologies and emerging technologies and try to forecast what kind of levels we might expect by the year 2000. I think that would be a very worthwhile endeavor that the National Academy would probably be very capable of doing.

Senator STEVENSON. That was my next question. The National Academy would be the appropriate place?

Dr. THALER. It seems to me it is certainly one of the places that could draw together the necessary expertise in the various disciplinary fields to give this thing a thorough going over.

Senator STEVENSON. If there are no further questions, thank you very much.

Dr. THALER. Thank you, Mr. Chairman.

[The statement follows:]

STATEMENT OF WILLIAM J. THALER, ACTING DIRECTOR, OFFICE OF TELECOMMUNICATIONS POLICY, EXECUTIVE OFFICE OF THE PRESIDENT

It is a pleasure to be here today to discuss the Government's program to assess the biological effects of nonionizing electromagnetic radiation.

OTP's involvement in electromagnetic radiation research stems from the dependency of telecommunications on the use of the radio frequency spectrum. The Director of OTP is responsible for advising the President on national telecommunications policy and on the Federal Government's use of telecommunications. An important component of these responsibilities is OTP's mission to coordinate telecommunications activities and associated research and to develop programs which will promote the use of telecommunications in the public interest. Insuring that the use of nonionizing electromagnetic (EMR) energy does not harm man or his environment is a integral part of this responsibility. OTP oversees a valuable national resource—the EMR spectrum—and is also interested in seeing that the vital and beneficial services the spectrum makes possible are not unnecessarily curtailed or impaired.

The Federal program, coordinated by OTP, is designed to develop a sound scientific understanding of the interaction of EMR energy with living systems. This will serve as a basis for evaluating possible biological risks of various levels and conditions of EMR and for developing appropriate controls which may be warranted to insure safe and effective use of the spectrum. Since its formation, this Office has had a vital interest in a strong Federal research program in this area. We recommended 5 years ago and undertook the coordination of a cooperative multiagency program to investigate biological effects of this energy so that there would be no unintended or unknown effects.

Our efforts involve radio-frequency radiation (i.e., 0–300ghz). Like visible light and infrared, these radiowaves are nonionizing radiation. Regrettably, the use of the term "radiation" often elicits confusion between this energy and ionizing radiation such as X-rays and nuclear radiation. However, there are important differences which determine how these different radiations interact with the body and their potential for causing harm. For example, a quantum, or individual bundle, if radio frequency energy contains far less (i.e., approximately a million times less) energy than a quantum of ionizing radiation which can break molecular bonds, produce ionization and do significant biological damage.

The use of radio-frequency energy has been growing rapidly. Today the radio spectrum is a widely used and integral part of modern society. It supports such telecommunications services as radio and TV broadcasting, citizen band radio, radars, air and marine navigation and safety systems, and emergency medical services. The spectrum also is used in industrial processing, medical equipment, and consumer products.

We have been working with nonionizing electromagnetic radiation since the days of Hertz in 1890. The first two decades of the 1900's saw the commercial and military uses of this radiation become a reality. The development of more powerful and diverse emitters using a wide range of frequencies during World War II stimulated further advances in this technology and its applications--thus increasing the potential for exposure to EMR. Yet, by the mid-1960's, our knowledge of the biomedical activity of nonionizing radiation was still very limited.

The major U.S. effort to increase that knowledge between 1957 and 1961 was a Tri-Service Program supported by the Department of Defense. It had been known for some time that radio-frequency radiation at sufficiently high levels could cause harmful effects through energy absorption and heating. Studies were conducted in the Tri-Service Program which demonstrated some of these harmful effects at power density levels around and above 100 mW/cm^2. Effects of thermal stress on the body's heat dissipating capability were also studied. These studies contributed to the acceptance of 10 mW/cm^2, based primarily on thermal considerations, as a permissible exposure limit below which harmful effects would not be expected to occur. This level has since become the basis for present standards in the U.S. and most Western countries.

Following the Tri-Service Program, non-ionizing EMR research came to a near standstill in the U.S., with the exception of a few isolated studies which included some investigation of biological effects at lower radiation levels. In this period, there was an increasing awareness of apparent differences between United States and Soviet concepts of the levels at which hazards from non-ionizing radiations occurred. While our literature showed harmful effects from short exposures at high milliwatt levels, the Eastern literature claimed harmful effects in the range of several milliwatts/cm^2, and in some cases, even microwatt/cm^2 levels. Also, the Eastern countries had established standards with maximum permissible exposures considerably lower than ours. They reported a wide range of observations (for example, effects on the nervous system and behavior), differences between various frequencies and waveforms (e.g., pulsed vs. continuous wave), and effects from lengthy exposures to levels below those generally associated with measurable or significant heating. We had no comparable research or basis for comparison and evaluation. Their publications frequently did not contain full information nor has there been a clear statement of the basis for their standards. However, our interest has led us to make a principal focus of our research since the mid-1960's the question of whether or not biological effects can be caused by EMR mechanisms of interaction with the body other than heating (nonthermal). Also, regardless of the mechanism involved, we want to know whether harmful effects can occur over a wide range of EMR conditions including lower radiation levels than we had previously anticipated. The Soviet research has been used to provide some initial guidelines in determining our present research priorities.

Toward the end of the 1960's there was a convergence of attention and concern by the Government, the scientific community, professional groups and industry on the biological effects of nonionizing radiation. In 1966, for example, the ANSI standard was issued; in 1968 a major industry report pointed to the need for a "central interdisciplinary coordinating body" in the "side effects" area, and Public Law 90-602 was enacted.

In 1967 the Office of Telecommunications Management, the predecessor to OTP, held discussions with academic, industrial and government personnel and initiated efforts to provide a central focus and review in this area. As a first step, the Electromagnetic Radiation Management Advisory Council (ERMAC) was established. It was made up of individuals with expertise in the various pertinent technical disciplines—biomedical and physical sciences and engineering—to advise and make recommendations on the adequate control of undesirable "side effects" associated with the use of the spectrum. The Council conducted an extensive review of scientific knowledge, requirements, and the status of research programs and funding. They recommended guidelines, initial research priorities, a framework for studies, and increased funding for a coordinated program of investigation among responsible Federal departments and agencies.

The 1971 ERMAC report reviewed the background and rationale for this research and emphasized its importance with remarkable foresight, for it has continued to provide valuable and comprehensive guidelines for research in this area. As a basis for determining future research requirements, the ERMAC continually reviews program activities on the growing state of knowledge of health effects. The Council is now in the process of reviewing its first five year plan in light of more recent research and is preparing updated guidelines for future efforts.

The research program was structured to take advantage of existing agency responsibilities and capabilities—although no single agency has this area as a principal mission, several departments and agencies do have relevant missions. Agency missions and operational needs were viewed as incentives to utilize their technical capabilities to conduct research. However, research was fragmented, funding was limited, and there was little, if any, interagency interaction. In order to use available resources effectively without distorting the priority of this research, ERMAC recommended that OTP, as an independent and impartial entity in the Executive Office, serve as an overview and coordinating body, with assistance from the Council. The OTP role includes emphasizing the importance of this research priority among other competing agency priorities, and attempting to ensure that the overall program goals are being adequately addressed.

At its inception, the ERMAC recommended program expenditures of approximately $10–15 million/year over a 5-year period for a coordinated Government-wide research effort. This recommendation was coordinated with OMB and the heads of departments and agencies for implementation by fiscal year 1974 or earlier to the extent practicable.

The basic program objectives continue to be:

To determine what biological effects radio frequency radiations cause under different conditions of exposure. For example, what are the effects of various frequencies, waveforms, energy levels, electric and magnetic field components, and exposure durations, and what is the possible influence of such biological considerations as age, sex, and health?

To determine the health and biological significance of any effects and to evaluate risk, with reference to realistic exposure environments.

To establish a sound scientific basis for any remedial and/or control measures which appear needed.

And, of course, to ensure that U.S. safety criteria provide an adequate margin of safety.

Where do we stand today? In many ways this program represents a unique approach to interdepartmental responsibility. I would like to touch briefly on our views of some of its accomplishments, its current status, and its problems. Additional information is contained in four summary reports issued by OTP.

Let me emphasize first that the research program, to date, has identified no positive evidence of harmful effects to man at the levels of exposure normally encountered by the general population. No crisis has been found to exist; no cause for public alarm has been identified; no specific mechanisms of interaction other than heating have been demonstrated. We must, however, be absolutely sure that nothing has been overlooked and we recommend continued and accelerated pursuit of the necessary research.

Mr. Chairman, I am pleased to be able to tell you that there have been some real accomplishments since this Committee's hearings in 1973. We do not yet have all the answers, but we have laid a solid foundation for developing them—in terms of the research capabilities that have been developed, the advances in the research itself, and the establishment of mechanisms for coordinating and pursuing this research.

We have succeeded in creating an Executive Office focal point and central forum for Government activities related to the biological effects of radio frequency radiation. This coordinated effort has given the additional identity to individual agency activities of being part of a larger program. It has also stimulated communication and exchange of information and interaction among the responsible government entities.

Each agency has designated representatives who meet with the ERMAC and serve as members of an interdepartmental working group. These individuals are identifiable and knowledgeable points of contact for activities in this area within their own agencies as well as with other agencies and the private sector.

Relevant research has been identified at the work unit level and organized to facilitate analysis and coordination of research efforts. This information is exchanged and available to all agencies, including those not actively engaged in research. It serves as a basis for technical reviews and for individual agency program planning and possible collaboration or mutual support of work which may be beyond the available resources of a single agency.

This, of course, is still a developing field of scientific endeavor without a large number of trained and highly skilled practioners ready to undertake research. Moreover, it involves highly complex technical problems and requires multidisciplinary skills. Since this Committee's previous hearings, there has been a considerable increase in both the level of technical sophistication and the numbers of investigators active in this research. Nonetheless, there is still a need to attract new investigators from various disciplines into this field.

There has also been an increase in exposure facilities available to conduct research over the wide range of frequencies and waveforms of interest. These facilities, including associated equipment and animal holding capabilities, are costly and required a considerable portion of the available research dollars, particularly at the outset. However, there remains a need for additional investment in facilities, particularly for studies involving long-term continuous or near continuous exposures.

In the actual conduct of the research, substantial progress has also been made. Better instrumentation and techniques have been developed for determining radiation dose and for measuring electromagnetic fields. These advances are critical to our ability to associate biological responses with exposures and to permit the extrapolation of animal experiments to man.

I am not going to elaborate here on specific research or results since I believe you have had the opportunity to hear from some of the agencies and investigators actually carrying out the work. However, I would like to point out that non-ionizing EMR research is far more complex than ionizing radiation. There are difficulties in relating absorbed energy to the incident radiation or "exposure." It is even more difficult to determine the distribution of that energy within the body. The body has different properties than air. It consists of different layers and structures of complex geometries and differing electrical properties which affect the internal distribution of absorbed energy. Frequency is very important as the degree of energy penetration is a function of the frequency; also there are questions about frequency dependent effects and resonances. We must also consider the effects of continuous wave emitters, pulsed emitters, and various other modulations and frequency combinations.

In the course of this research, biological effects have been observed and reported in experiments with small laboratory animals at levels around and even below 10 mW/cm^2 (e.g., in the range of 1–20 mW/cm^2). These effects include changes in learned behavior or task performance, radiation perception, and apparent alterations in electrophysiological measurements of nervous system activity.

While reports of such biological changes evoke considerable interest because of the level of current safety standards, they do not necessarily imply hazards to man for many reasons. For example, differences in size, geometery and physiology between humans and laboratory animals with respect to frequency and power density and the nature of an effect are among many factors which need to be taken into consideration in assessing or interpreting this research. Nevertheless, systematic study must continue to be vigorously carried out to determine under what conditions any biological effects occur and what their significance is to man.

In assessing the impact of this radiation on man one must develop a realistic picture of actual exposure environments and the populations which are involved. The EPA, DOD and other agencies have been conducting programs in this regard. While their work is still in progress, and actual measured data is somewhat limited, it appears that radiation levels in most environments normally encountered by the general public are well below 10 mW/cm^2, although levels of a few milliwatts/cm^2 do occur in some occupational situations. In fact, the EPA has estimated that approximately 99% of the general population is not normally exposed to levels exceeding 1 microwatt/cm^2 (which is 10,000 times less than 10 mW/cm^2).

Further hallmarks of a maturing effort include an increase in research in areas which have evolved out of EMR research itself and more studies to replicate observations. Studies are now being conducted with longer radiation exposures, although we need more work with still longer exposure periods. Also, the United States and U.S.S.R. have recently established an agreement to conduct collaborative research in the microwave area.

Our experience over the past few years has also made it possible for us to identify some of the problems and deficiencies in this effort. In our opinion, the major problem is that non-ionizing radiation research requires greater priority. Sufficient and stable funding is needed to attract new investigators, to develop exposure facilities and instrumentation, and to permit timely follow-up of project findings, experiments with long-term exposures, and studies of people who encounter non-ionizing radiation in occupational situations. Current funding is approximately $9 million per year. HEW, EPA and DOD account for approximately 90 percent of these funds.

Let me illustrate some of the problems:

EMR research has had to compete for resources within each agency against many other priorities, some with greater agency or public interest priority.

Research requiring relatively large and stable funding, such as experiments within long-term chronic exposures and large epidemiological studies, is beyond the particular resources of any individual agency for non-ionizing radiation research.

Certain types of research, for example, basic research, are not being funded at a high enough level because of the mission orientations of some of the agencies.

We are all aware of the increased attention and apprehension over the question of the safety of microwaves and other non-ionizing EMR. However, it is important to maintain a proper perspective.

Undertaking a research program in itself can imply that a hazard is either known or suspected. The development of a research effort means more investigators, scientific publications and public presentations, involvement of professional groups, and, hence, greater visibility. This visibility has led to more publicity in the popular press. However, because of the complexity of the topic, information is sometimes limited, out of context, and, as a result, difficult to interpret.

Even with all of the available information, interpretation of research results and their significance for man is complicated. Consideration must be given to such things as: the number of observations of a phenomenon; whether a finding can be repeated in the same or another laboratory; how findings in various laboratory animals can be related to man; and, whether an observed change or effect, in fact, constitutes a hazard. One must also distinguish preliminary findings from results of completed research and avoid drawing conclusions based on work still in progress.

The apparent differences in Eastern and Western research and safety standards also contribute to confusion. While we do not know the precise reasons, these differences may, to some extent, be due to different approaches to the development of standards and the definition of a "hazard." We hope that our recently increased contacts and cooperative research with Soviet scientists will help to resolve some of these apparent differences.

Finally, the use of the term "low-level" has created misunderstandings. It has often been indiscriminately applied to levels from fractions of a microwave/cm^2 to 10 mW/cm^2 and above (a range of more than 10,000). Levels of a few microwatt/cm are very high levels in communications or interference terms.

In summary, research to date has not demonstrated that any hazard to the general population exists. However, many questions remain unanswered, including some raised by the research we have conducted to date. Resolutions to these questions and experience gained make it possible to identify outstanding research needs and priorities. These are:

experiments to investigate effects of long-term, relatively low-level exposure;

studies of people exposed in specific occupations or special environmental circumstances;

increased investment in basic research, including investigations of mechanisms of biological interaction;

additional development and refinement of techniques and field measurement capabilities for determining radiation dose, for measuring internal energy fields and energy distribution and for interpreting laboratory findings to man.

Our goal should be a productive effort which continues to make effective use of the capabilities already developed by the agencies and makes it possible for them to meet the research objectives of this program.

In conclusion, I believe that a continued vigorous program of research based on long-term stable funding is necessary to develop a sound scientific basis for evaluating any possible biological effects from non-ionizing radiation, particularly at a time when use of the radio frequency spectrum is growing so rapidly. Further, I feel it is important that we assure that any regulatory or control measures be based on both demonstrated need and sound scientific judgment so that we can be sure that we have best served the total public interest.

[The following information was subsequently received for the record:]

OFFICE OF TELECOMMUNICATIONS POLICY,
EXECUTIVE OFFICE OF THE PRESIDENT,
Washington, D.C., October 20, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: It was a pleasure to have the opportunity to testify before your Committee on the mater of nonionizing electromagnetic radiation effects. This is an important area which can have far reaching impact on our society. Continuing efforts to coordinate and ensure adequate support for responsible action—research, assessment, and regulatory—by the Federal Government are essential if we are to resolve the complex scientific questions and issues in this area in the public interest.

Responses to the specific questions in your letter of August 15 are contained in Enclosure 1.

We appreciate the opportunity to contribute to your review and your interest and support of work in this important area. We will be happy to provide any additional information you may require.

Sincerely,

WILLIAM J. THALER,
Acting Director.

Enclosure.

The following are responses to the specific questions posed in your letter:

Question. When will the ERMAC's review of the first five year plan be completed?

Answer. It is currently anticipated that the ERMAC's updated and revised program recommendations/guidelines will be completed by January 1978.

Question. How many agencies currently divide the $9 million available for research?

Answer. The estimated Federal expenditure is comprised of the independently funded efforts of 9 Departments/Agencies. (This does not separately count the 3 components of HEW and DOD, as shown below.) As can be seen DOD, HEW and EPA account for somewhat more than 90 percent of the funds and effort. Dollar figures should be viewed as approximate because of the differing fiscal/budgetary procedures of the various entities particularly for inhouse efforts—e.g., some agencies include all manpower and associated overhead whereas others (such as DOD) are "program dollars" only and do not include costs of military personnel, etc. (The National Cancer Institute and NASA/ERDA which have some relevant research, and OTP/OT are not included below).

FUNDING IN PERCENT

Department/agency	Fiscal year—		
	1976 plus transition quarter	1977	1978[1]
DOD	60.4	63.4	66.4
Army	10.2	9.8	9.6
Navy	39.2	40.4	40.5
Air Force	11.0	13.2	16.3
HEW	20.9	18.0	16.6
BRH	15.1	12.3	9.2
NIEHS	4.5	4.8	3.5
NIOSH	1.3	.9	3.9
EPA	13.0	14.1	11.3
NBS	1.6	1.8	1.7
NSF	2.8	1.2	2.1
FCC			
FAA			.2
VA	.9	1.1	1.0
CIA	.3	.3	.3
Amount (millions)	$9.2	$8.5	[1]$9.3

[1] Estimate.

Question. The electromagnetic radiation emanating from man-made sources has increased phenomenally since World War II. In 1973, your office estimated that U.S. government depreciated capital investment in communications and electronics exceeded $50 billion. What do you estimate current investment figures are?

Answer. The current (1977) estimated U.S. Government depreciated capital investment in electronics is $67 billion. This is an increase of $6 billion from the 1973 estimates. It can be expected that the incremental non-depreciated estimates of U.S. government electronics investment will range from $14.8 billion in 1977 to $19.5 billion in 1986, (ten year forecast using constant 1978 dollars). Of this yearly increase, all but about $2 billion/year is for DOD investment. The estimated U.S. government depreciated capital investment in electronics by 1986 will be $99 billion.

The $50 billion figure was a 1973 estimate for that portion of the electronics investment which is radio spectrum dependent. The best overall estimate now available (through 1976) is $52.4 billion (U.S. government) and $54.7 billion (non-government). It is projected that the 1977 estimate for radio specturm dependent equipment (U.S. government) will be $55.2 billion. No 1977 estimate is readily available for non-government radio spectrum dependent equipment.

Question. Suppose we find that microwave radiation does cause deleterious effects. Are there any emerging technologies such as coaxial cable and fiber optics which could be substituted for our heavy dependence on microwave sources? Please describe in further detail.

Answer. According to the Environmental Protection Agency, the most prevalent source of general public exposure to radiowaves are the broadcast transmissions of television and FM stations. Technically it would be possible to eliminate this exposure by the use of coaxial cable (already begun on a small scale) or fiber optic cable for transmission of the broadcast signals. It has been often suggested that such a replacement, for reasons other than biological harm concerns, would be desirable. Coaxial and fiber optic systems could provide improved service to the public simply by their ability to provide more chanels for programming. Such closed transmission systems would improve, substantially, the quality of the signals in that topography, structures, and weather would have no effect on the signals. Although such replacement is technically feasible, it would be accompanied by intense economic, regulatory, and legislative problems, particularly with respect to sparsely populated areas where the per-household costs of replacing over-the-air broadcast service can be much higher than in metropolitan areas. Finally, the removal of on-the-air broadcasts would free the presently allocated spectrum to be used for services that cannot be linked by cables or fibers, e.g. communication to aircraft, spacecraft and ships and land vehicles.

It would be possible to replace other sources of microwave radiation, such microwave relay transmissions, by cable. Such transmissions, however, are even weaker than broadacst signals. It is difficult to imagine that such levels are harmful to the general public. Additionally relay systems require no obstruction in their path and so are highly directional with minimal radiation outside of the primary beam. Likewise a substantial part of the satellite communications now in use could be replaced by cables, fibers, or millimeter wave guide; for example, a satellite communication network from New York to San Francisco. The present use of satellites, between fixed terminals within the 48 states is dictated primarily by economic advantages. Other technologies which may ultimately play role are through-the-atmosphere optical communications and "Hertzian Cable."

As mentioned previously, a number of services cannot be transferred to cable or fiber systems simply because at least one end of the transmission path is moving. Such services include mobile communications, radar for radio location, and radio navigation systems. In urban applications, there are some emerging technologies that would allow mobile units to transmit over short distances to relays which would distribute the signals to more remote relays by cable or fiber means. Obviously such innovations would offer only a partially reduced environmental radiation but they would alleviate problems of radio interference. Any system which must radiate through the atmosphere can be optimized to lowest possible levels by the use of sophisticated modulation schemes and appropriate receivers. However this would involve considerable increases in complexity, initial costs and maintenance.

The need for alternative technologies and the extent of any such use would be influenced by what electromagnetic field exposure conditions—frequency, waveform, power density, time, etc.—might be found to be responsible for any harmful effects. For example, a finding that such effects occur only under certain conditions (of frequency, etc.) would affect any such considerations.

Question. You recommended experiments to investigate effects of long-term relatively low-level exposure and occupational studies. But in your discussion of problems relating to the research program on the bio-effects of electromagnetic radiation, you mentioned that research requiring relatively large and stable funding, such as the low-level chronic effects and large epidemiological studies, are beyond the particular resources of any individual agency. Would OTP choose one agency that would be particularly suitable for conducting these sorts of studies, and recommend that there be commensurate budget increases?

Answer. Experiments involving long-term, chronic exposures—particularly continuous or near-continuous exposures—and epidemiological studies of occupational or other special population groups are costly and beyond resources currently available in the individual agencies for radio frequency microwave research. In both cases there are various conditions and situations requiring extended investigations. Research should be carried out where the best capabilities exist for conducting and/or managing the particular study in question. Specific determinations should be made on the basis of matching agency mission and technical and management capability with the specific task required. Broad guidance should be provided by a national advisory group which includes a broad range of scientific expertise and opinion and recommends parameters and priorities for such studies taking into account, for example, significant frequency ranges, exposure conditions, and biological/physiological or health endpoints of concern.

Several agencies have capability to carry out large-scale experiments with long-term exposures—namely HEW, EPA and DOD. The mission/program orientations of various entities are a consideration, particularly in terms of frequency or electromagnetic conditions to be studied. For example, a study involving electromagnetic pulse (EMP) exposures would be more logically carried out by, and be of, greater interest to DOD than to BRH, EPA or NIEHS. These considerations apply to both in-house as well as intra-mural programs as there should be some logical association with the supporting agency's program interests and responsibilities. Collaborative efforts involving funding and/or expertise of more than one entity should also be considered where appropriate. In particular, there should be a buildup in non-defense non-regulatory agencies for such work.

Similarly, epidemiological studies would best be carried out by those Departments/Agencies with relevant responsibilities and capabilities for this type of research. HEW, EPA and DOD all have capabilities if they could be made available for this work. Several HEW components have expertise and experience with human studies in a wide variety of fields. NIOSH has a responsibility for occupational and employment related health and safety. Other HEW groups and EPA would be logical candidates for conducting health studies, particularly of general population groups. Consideration should be given to utilizing capabilities in groups (government and nongovernment) not necessarily now involved in microwave research but possessing needed epidemiology expertise such as the National Center for Health Statistics or, perhaps, the Center for Disease Control (CDC). DOD also has strong environmental and preventative medicine interests and capabilities as well as having some of the potential occupational populations of high interest. Cooperative efforts should also be considered, for example between agencies with field measurment and survey capabilities such as EPA and groups, such as the National Center for Health Statistics or CDC, to ensure availability of the full range of capabilities and skills required.

Question. During the course of your oral testimony you mentioned that ideally you would support expenditures from $18 to $27 million as opposed to $9 million now spent on research programs. Could you amplify this comment? In an ideal world, which agencies and research programs would you allocate the extra dollar amounts?

Answer. This rough estimate[1] 2–3 times present levels, was based on unlimited budget authority and took into account research desires, the extent of the research community, the state of development of the field, and the experience of the research program over the past few years. For example, as noted in our letter to Sens. Ford and Stevenson of June 10, 1977, and in testimony, additional resources would be helpful in studies involving long-term chronic exposures, additional studies of basic mechanisms of interaction between EMR fields and living systems, studies of occupational or other special population groups, and further development and refinement of dosimetry which is critical to interpreting results of animal experiments and their relevance to man (as well as timely followup of research findings). Specific determinations should be based on the capabilities of the agencies and the particular research. The ERMAC is considering the matter of program requirements in preparing their revised recommendations.

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[1] A similar estimate is made by the Second Task Force for Research Planning in Environmental Health Science.

Question. In oral testimony, Ms. Healer offered as an explanation of the difference between the Soviet and the American exposure standards, that the two may fundamentally differ on the definition of hazards. Please provide amplification of this statement.

Answer. While we do not know the precise basis and rationale underlying the Soviet standards there are indications that, to some extent, differences may be due to different philosphies and approaches to the development of standards and interpretation of "effects" in terms of "hazards." In discussions with Soviet scientists they have expressed the view that deviations, be they increases or decreases, in any naturally occurring factor in the environment in which man evolved are anticipated to produce a change or "effect." This prior view is not generally shared by U.S. scientists. Our approach would be to see whether a particular circumstance does or does not have an effect.

Additionally, it is important to distinguish between a "change" or "effect" and a "hazard." A biological or physiological change or effect does not necessarily constitute a "hazard." Numerous examples in our daily lives can be cited. For instance, running up a flight of stairs, or other moderate exercise results in a host of physiological "changes" such as increased heart rate, circulatory and respiratory effects, etc. which are not considered hazards under normal circumstances. Soviet scientific publications and, more recently personal discussions, suggests that the Soviets may use *any* physiological changes, even transient and subjective symptoms, as a basis for establishing safety criteria some appropriate order of magnitude below the lowest level at which such phenomena are found to occur. We generally look for objective signs and pathology and base our determinations of what constitutes a "hazard" on such objective criteria as a point of departure for the establishment of safety standards or criteria. It should also be noted that there is some ambiguity in the realm of field measurements and dosimetry. Many of the early Soviet publications upon which their present standards are based are not explicit as to how the field intensities associated with a reported observation were determined. This lack of information has made it difficult to evaluate the validity of some of these reports.

From our own experience we know that measurement techniques and dosimetry were not well developed in earlier work in this country and that this led to misleading conclusions. Different measurement techniques and the specifications of exposures may account for some of the differences.

Recent contacts indicate that the Soviets are undertaking additional research to reassess their conclusions and the scientific basis for their safety standards.

In any event, it is hoped that recently increased East-West contact and collaborative research will provide further insight into Soviet observations and the differences in our standards.

Question. In the course of your oral testimony Senator Schmitt asked for possible research and biological effects of intense magnetic fields. You responded that you knew of one researcher at the University from which you came involved in this sort of research. Please provide the Committee with a summary of this study and any others that you may know of.

Answer. The study referred to has been published as "Evidence of Morphological and Physiological Transformation of Mammalian Cells by Strong Magnetic Fields," by G. I. Malinin, W. D. Gregory, et al. A copy is attached.[2] In this study mammalian cells in frozen culture to 4.2°K were exposed for 4–8 hours to 5000 Oersted. Growth inhibition was observed and morphologically distinct cells were propagated through several generations. It should be noted that a field of this magnitude is a highly unusual environment and would be expected to be found only in the interior of electromagnetic systems specifically designed to operate at high fields.

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[2] See *Science,* vol. 194, pp. 844–846, Nov. 19, 1976.

A source of additional references to magnetic field effects is *Biomagnetic Effects: A Consideration in Fusion Reactor Development*, D. Dennis Mahlum, Battelle Pacific Northwest Laboratories, Richland, Washington, for ERDA), Rept. No. BNWL–1973 UC–20, February 1976.

Senator STEVENSON. Our next witness is Charles Hardin, member and past chairman of the Conference of Radiation Control Program Directors and manager of the Kentucky radiation control program.

STATEMENT OF CHARLES HARDIN, MEMBER AND PAST CHAIRMAN, CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS AND MANAGER, KENTUCKY RADIATION CONTROL PROGRAM

Mr. HARDIN. Thank you, Mr. Chairman.

Mr. Chairman, members of the committee, I am Charles M. Hardin, manager of the Kentucky radiation control program, Frankfort, Ky. I am representing the Conference of Radiation Control Program Directors, an organization whose membership is comprised of all directors of radiation control programs in the 50 States, certain territories and large municipal agencies.

This conference is pleased to have been asked to testify before this committee on the vital subject of radiation health and safety. Mr. Chairman, I have submitted detailed written testimony for the record. However, the written document is too lengthy to read, but I would like to highlight some of the key issues presented in that written testimony.

Senator STEVENSON. Thank you.

The full statement will be placed in the record.

Mr. HARDIN. To properly understand the concerns of the conference, and its role in relation to State radiation control programs, a brief history and description may be helpful.

The Conference on Radiation Control Program Directors was formed approximately 9 years ago to serve as a forum for the exchanging of radiation health and safety information, between State and Federal agencies, as well as between States themselves. The conference is primarily supported by three Federal agencies; the Food and Drug Administration, the Environmental Protection Agency, and the Nuclear Regulatory Commission. We are also participating in projects of the National Bureau of Standards. The conference has served as a coordinating point on radiation health matters with several other Federal agencies such as the Department of Labor, the Energy Research and Development Administration, the Department of Transportation, and others. Additionally, the conference has liaison with the American College of Radiology, the American Society of Radiologic Technologists, and the American Registry of Clinical Radiography Technologists.

The overall goal of the conference is to assure that the patient who is to receive radiation, either diagnostically or therapeutically, the worker in radiation, the consumer, and the general public at large, receives the lowest amount of radiation exposure consistent with the benefit derived from such exposure.

In keeping with this goal, and the policy of serving as a forum for the exchange of information, the conference establishes task forces to evaluate, discuss, and subsequently to recommend specific actions to resolve identified problems. These task forces have representative membership from both State and Federal agencies. They may also have representation from professional associations and industry. Although, I do not have sufficient copies for the entire committee, for the record, I would like to submit two examples of reports from these task forces. The first is "Task Force Report on Bonding & Perpetual Care of Nuclear Care of Nuclear Licensed Activities," the second is a draft of the "Task Force Report on Natural Radioactivity Contamination Problems."

These task forces not only meet throughout the year, but they present their report at the annual conference meeting so that the conference may review and consider any recommendations made by a task force. Proceedings of these annual meetings are published, and again, although I do not have sufficient copies for the entire committee, I would like to submit the published proceedings of our last eight annual meetings. These proceedings will identify the issues considered by the conference, and the actions taken to resolve identified problems.

Mr. Chairman, at this time I would like to share with the committee some of the basic facts on State government's involvement in radiation health and safety. State radiation control began to develop in the early 1950's. Early impetus began principally with Federal support in the areas of model legislation, grant funding, and training programs for the States. Most attention in early State activity was concentrated in the areas of X-ray use and occupational exposure. Almost concurrently, State interest developed in the control of radioactive materials. This interest was addressed by Congress in 1959, by amending the Atomic Energy Act, which allowed for State participation in the control of byproduct, source, and special nuclear materials. The amendment permitted State participation by becoming an "agreement State."

As of June 30, 1976, all but two States, Puerto Rico, and the District of Columbia had enabling acts for radiation protection regulations. Twenty-five States have signed agreements with the Nuclear Regulatory Commission under authority of the Atomic Energy Act, as amended. Also, as of June 30, 1976, 45 States, Puerto Rico and the District of Columbia had regulatory programs in medical/dental X-ray control, with 43 States, Puerto Rico and the District of Columbia having regulatory programs in industrial X-ray control. As of June 30, 1977, 12 States and Puerto Rico had enabling legislation for the credentialing of the user of X-rays. Of this number 3 States and Puerto Rico have implemented credentialing programs, with 2 States scheduled to become operational in the immediate future. Eight other States have proposed legislation relative to use regulation.

In the area of nonionizing radiation, as of June 30, 1977, 21 States had specific statutes relating to the control of nonionizing sources.

In regard to resources expended at the State level for radiation control, for fiscal year 1975 over 523 man-year equivalence were employed.

During fiscal year 1975, over $11 million was expended by States in radiation protection activities.

One of the major radiation protection activities at the State level is the inspection of radiation sources for compliance with established health and safety regulations. For fiscal year 1975, over 25,000 dental and over 27,000 medical X-ray inspections were made. In addition, over 3,000 inspections were conducted for proper use of radioactive materials.

For more detailed analysis of State activities in radiation control, I would like to submit a copy of an FDA document "Report of State and Local Radiological Health Programs" for fiscal year 1975.

Senator STEVENSON. All of these submissions will be retained in our records.

Mr. HARDIN. Thank you.

A similar report for fiscal year 1976 should become available within the next few weeks. Mr. Chairman, the aforementioned facts and figures were to emphasize that States are involved in numerous and varied aspects of radiation health and safety.

At this time I would like to discuss the current radiation issues which the conference perceives that need addressing. These current issues, in their order of priority are:

1. The reduction of unnecessary radiation exposure from X-rays used in the healing arts. We believe that the main contributing factors to this unnecessary exposure are: (1) inadequate training in radiation protection by both the operators of X-ray sources and the nonradiologist practitioner; (2) the nonefficacious use of X-ray sources; (3) inadequate quality control programs in X-ray facilities, resulting in retakes of radiographs, and (4) improperly designed X-ray systems.

2. The reduction of unnecessary radiation exposure from radioactive material used in nuclear medicine. We believe the main contributing factors in this area are: (1) inadequate training in radiation protection; and (2) nonefficacious use of certain radioactive materials relative to other materials.

3. The reduction of unnecessary radiation exposures to the general population from various environmental sources, both ionizing and nonionizing. Examples of sources which we believe contribute to this environmental exposure are: (1) ionizing sources existing in nature, such as radioactive materials in phosphates; man-made and natural ionizing sources from the uranium fuel cycle, particularly uranium mill tailings and radioactive waste; and (2) nonionizing sources such as microwave and radio frequency transmissions.

4. The reduction of unnecessary radiation to the radiation worker, both from ionizing and nonionizing sources. Of particular concern for the worker is the use of both radioactive materials and X-rays in industrial radiography, and the use of the X-ray in medical fluoroscopy.

5. The reduction of unnecessary radiation exposure to the consumer public from both ionizing and nonionizing sources. Examples of ionizing sources in this area are the color television, which may emit ionizing radiation incidental to its primary use; and in the nonionizing area, microwave ovens. It would appear that industry is properly manufacturing these sources to meet FDA emission standards. How-

ever, there does appear to be a need for standards on microwave exposure limits for people, in addition to source emission standards.

6. The problem of laser radiation, a nonionizing source used in industry and educational institutions should not be overlooked. The conference feels this source represents a potential for unnecessary exposure to workers, students, teachers, and in some cases, the general public-at-large.

In addition to the six major radiation protection issues discussed above, the conference considers four specific programmatic problems should be brought to your attention.

1. Loss of State training from the Federal Government.—In the 1960's and early 1970's State radiation protection personnel received excellent training, either directly or through training grants from the Federal Government. Currently, with the exception of training supported by the Nuclear Regulatory Commission, only very limited Federal support for training of State personnel has been available. This lack of training has been especially noticed in the areas of X-ray and environmental protection.

2. Overlapping Federal jurisdiction in radiation protection activities.—There are 12 Federal agencies which the conference has identified with some responsibility or activity in radiation protection matters. From a State's viewpoint, this Federal picture appears to be very confusing as to which agency has responsibility for a given area in radiation protection. In many areas, there appears to be overlapping jurisdiction resulting in possible duplication of efforts, and in some cases, different standards relating to the same area. Two typical examples are: (1) The development of X-ray guides and/or standards in medical X-ray. Both the FDA and EPA appear to have active programs in this area; and (2) the development of emergency radiation plans. There are at least six Federal agencies involved in this area; specifically, the Nuclear Regulatory Commission, Environmental Protection Agency, Housing and Urban Development through the Federal Disaster Assistance Administration, General Services Administration through the Federal Preparedness Agency, Department of Health, Education, and Welfare through the Food and Drug Administration, and the Department of Defense through the Defense Preparedness Agency.

I understand NRC is the lead agency in this area, but we still have difficulty communicating with all agencies.

In light of this confusing Federal picture, the conference adopted a resolution in 1973, requesting Congress to consider consolidation of the various Federal agencies in radiation protection. A copy of this resolution is submitted for the record. The conference currently supports the general concept of consolidation of Federal activities in radiation protection, although we realize that one single agency may not be feasible. This would be especially difficult and not recommended, to combine regulatory agencies with nonregulatory agencies.

As an option, if consolidation is not feasible, we would recommend clear and concise "memorandums of understanding" between the various agencies, as to what their responsibilities are, and which is the "lead agency" for a given area, when legislation requires more than one agency to be involved.

3. Loss of direct Federal financial support to State radiation control programs.—During the early and middle 1960's, funding to States for radiation control was through Federal formula grants. These funds stopped in 1968, and as a result many State radiation control programs have financially suffered. These programs, which protect the citizen from biological effects that may be long term, and for which protection service is difficult to demonstrate immediate effectiveness, have had to compete with our health planning money and revenue sharing moneys. Some State radiation control programs have had very little growth or expanded activities since. I should comment, however, that other State radiation control programs have expanded their activities under State-generated funds.

4. Lack of uniform national criteria and/or standards.—There is an urgent need for national criteria or standards in certain radiation protection areas. Two specific areas are:

A. The regulation and control of radioactive materials not covered by the Atomic Energy Act. Specifically, naturally occurring and machine artificially produced radioactive materials (NARM). There is a significant gap in this area of control. The potential for unnecessary radiation exposure from NARM is as great, and with some materials such as radium, possibly greater than from materials which fall under the Atomic Energy Act. Federal legislation may be needed for the uniform control of this type radioactive material.

B. The siting, regulation, and perpetual care of "low-level" radioactive disposal facilities. Of the six commercial "low-level" sites, five are under State regulatory control, and all land on which these sites are located is either directly owned by States, or in the case of one site, owned by the Federal Government and leased to the State. At all sites, it appears that State government has the responsibility for the long-term perpetual care. There is need for national guidance and criteria of what constitutes acceptable sites for the disposal of "low-level" radioactive waste.

The above stated issues and programmatic problems are what the Conference of Radiation Control Program Directors perceive to need some attention or resolution for the proper radiation protection of our citizens. In some cases, congressional action may be needed for the proper resolution of the issues or problems.

Thank you very much for providing the conference an opportunity to express the views of the State radiation control programs on this vital subject.

Senator STEVENSON. Thank you, Mr. Hardin.

What are those low-level radioactive wastes to which you just referred?

Mr. HARDIN. Sir, would you repeat that?

Senator STEVENSON. What are those low-level radioactive wastes to which you just referred? Can you give us examples?

Mr. HARDIN. Currently, Mr. Chairman, there is only one definition of high-level waste, which is defined by the Nuclear Regulatory Commission. It relates to the liquids from fuel reprocessing. Materials that do not fall under that specific definition then fall under what are called low-level radioactive wastes.

Senator SCHMITT. Mr. Chairman, if you will yield, we have been involved with this a little bit in New Mexico with a possible siting problem. A large part of it is just the discards; that is, the gloves and the materials that were used in handling radioactive wastes.

Senator STEVENSON. That's what I am trying to find out. What are they?

Mr. HARDIN. Specifically they may be materials generated in nuclear medicine programs of hospitals, in which there are contaminated gloves, contaminated chemical wipes, that kind of material. There may be waste generated from the power industry. Again, contaminated clothing, tools, this kind of material used in the industry, as well as in the nuclear medicine field.

Senator STEVENSON. You say there are only six such sites in the country?

Mr. HARDIN. Six commercial low-level sites. I believe there are five low-level sites within the Federal Government area, within ERDA.

Senator STEVENSON. So those low-level wastes must be collected and then transported also?

Mr. HARDIN. That's correct, sir.

Senator STEVENSON. To these sites.

Is there a problem of control during the collection and transportation states also?

Mr. HARDIN. I do believe that risk could be in the transportation of these materials, and this is also one of the concerns of States, that these materials are carried across our borders to the sites in a safe manner. Thus far, there has been very little problem that has developed, although there have been a few accidents with materials.

Senator STEVENSON. Do the States take an interest in release of radioactivity from coal mines?

Mr. HARDIN. I am aware in relation to coal, Mr. Chairman, of some studies done of radioactivity directly in coal mines by the MESA, an agency of the Department of Interior. I have copies of those which indicated there is very little concern from a radioactive viewpoint to coal miners. As regard to the release of radioactivity to the environment from the burning of coal, we believe that is one area in which research needs to be done. I am not aware of any levels.

Senator STEVENSON. You are not aware of any levels. Do the States monitor radiation at coal-fired generating plants?

Mr. HARDIN. Not to my knowledge, sir.

Senator STEVENSON. Would you support legislation such as Senator Randolph has introduced, setting Federal minimum standards for the licensing of radiologic technologists?

Mr. HARDIN. Mr. Chairman, I fully concur with the concept that there is a need for the credentialing of X-ray operators. I fully concur with that. I think the majority of the States concur with that. I do believe, if I understand Senator Randolph's bill, would require Federal control. I believe what the States would support primarily is Federal guidance in this area, the developing of proper, uniform criteria and guidance, but that the administration of such credentialing should be at the State level.

Senator STEVENSON. I think that is what the bill does.

Let me ask, what if the State fails to meet the minimum Federal standards? Under the Randolph bill, would the Federal standards be applied to the States?

Ms. NELSON. Under Senator Randolph's bill the States would have 2 years after the Secretary promulgates minimum criteria to submit letters of intent to adopt the Federal standards or more stringent regulations. If the States did not submit such letters of intent, the Federal minimum standards would go into effect.

Mr. HARDIN. As far as the conference's position, they certainly do support the need for the credentialing of the X-ray user and in many cases, the credentialing of the nonradiological type of practitioner, as well.

Senator STEVENSON. It sounds as if they would support the Randolph approach, which establishes minimum Federal standards, but leaves the credentialing to the States.

Mr. HARDIN. Mr. Chairman, I am not that familiar with the exact wording of it. The concept I certainly would support. Exactly as to the words in the bill, I would have to read it carefully before I could respond to that.

Senator STEVENSON. What can be done to assure that physicians do not prescribe unnecessary X-ray exams?

Mr. HARDIN. Our recommendation there, the conference's recommendation would be—this is an area of medical practice and not a field of radiation protection in our area. The recommendation would be that studies be done by the medical profession. I understand the American College of Radiology has been studying the area of the efficacious use of X-rays. I would certainly recommend such studies be continued by the medical profession with guidelines from the medical profession as to what are efficacious uses of X-rays.

Senator STEVENSON. What more can be done to assure that equipment manufactured prior to the promulgation of the BRH standards is properly maintained and calibrated? I don't know why that question is confined to equipment manufactured before. I think equipment manufactured both before and after needs to be supervised. Based on prior testimony, we should maintain it up to standards.

Mr. HARDIN. The BRH recommendation is for the manufacture of new equipment. The States have programs to inspect and have regulations to control the use of the X-ray machines once they are out in the world being used.

Presently, I believe that most State programs have an adequate X-ray program to address the use of the old equipment, and several States are currently participating under contract with FDA to inspect the new manufactured machines that come out on the market. Possibly more States could be involved in the participation with FDA and the inspection of this X-ray equipment. If the budget of some States is expanded, they could possibly increase their surveillance of used and old equipment in the field.

Senator STEVENSON. You showed, for fiscal 1975, over 75,000 medical and 25,000 dental X-ray inspections were made. Can you give us some idea as to what percentage of all X-ray units were covered by those inspections?

Mr. HARDIN. Yes, sir. That information is in the document.

Senator STEVENSON. Can you give us an estimate now?

Mr. HARDIN. I believe if I recall reading the document—and I would have to get it confirmed—I believe an estimate would be something like 20 percent. Again, I would have to confirm that through the document.

Senator STEVENSON. Roughly how often are these machines inspected, and is there any effort to inspect the older equipment more frequently than the newer equipment?

Mr. HARDIN. That depends somewhat from State to State. I can express to you how it is done in Kentucky. Maybe it would be a little representative of that.

The priority of inspections are set based on the kinds of equipment that are being used, particularly the number of people that are being exposed by that particular X-ray source and the kinds of problems that we have found in the past with that particular kind of facility.

This turns out to indicate that something like a hospital will try to be inspected once every 2 years. Other sources of X-ray, like the gauges that are used in industry, of course, would have a priority very low, maybe once every 5 to 6 years.

Senator STEVENSON. What do your inspections reveal about the safety of this equipment?

Mr. HARDIN. I would say the inspections today, the findings of equipment today are much better than they were when we started back in 1962 or 1963. However, we are still finding there are certain items of noncompliance with our regulations, usually of a minor nature, however, not of anything major.

So, in general, the equipment viewpoint of that radiation and safety is in a reasonably good shape today.

Senator STEVENSON. You mean the equipment manufactured today?

Mr. HARDIN. Yes, sir. The manufacture of equipment—although I understand from the BRH testimony, there was found significant noncompliance. From the States' level of inspection, particularly of the old equipment, we have found that the industry, the professional people have upgraded their equipment substantially since 1962 and 1963.

Senator STEVENSON. The FDA estimates that between 30 and 50 percent of the new machines don't comply with the new standard.

Mr. HARDIN. Yes, sir. That was the reference of the testimony I was referring to of 30 percent of noncompliance.

Senator STEVENSON. Your experience is at variance with that? You were indicating that problems with new equipment now were minimal.

Mr. HARDIN. No, sir. I think possibly I misrepresented the two kinds of equipment. The States have been involved with the old equipment since the early 1960's. What I was speaking of, in which there has been substantial involvement, is that old type of equipment from the 1960's that is now being used and upgraded.

Let me give you an example. In the early years of inspection of X-ray equipment, we found very poor collimation of the beam, where the X-ray beam should cover only the area to produce diagnostic information to the patient, we may have found a machine in which the entire beam would cover the face and possibly other major parts of the body.

Today—that was in the early 1960's. Today, we are finding that that kind of equipment has generally been upgraded to where there are a very limited number of machines that have that problem.

Now, with respect to the newly manufactured equipment under the Federal performance standard, our experience, I suppose, would support the Food and Drug Administration, since we are participating with them under contract with several States. I have not tried to break the statistics out as to equipment manufactured under the performance standard versus the old equipment I was speaking of earlier.

Senator STEVENSON. Senator Schmitt?

Senator SCHMITT. What do you think would be the capacity of the States to administer Federal standards if they had regulations?

Mr. HARDIN. I believe the State programs would be able, and have performed well under the contract with the Food and Drug Administration in the inspection of this equipment and have provided them with very valuable, competently done information on the inspection of these equipments.

Senator SCHMITT. Do you think all States are willing to assume that kind of responsibility?

Mr. HARDIN. No, sir, I do not. I asked this question to some of the State representatives, specifically. Some of the answers about not wanting to participate primarily, I think, center around what they feel might be short-term Federal funds in which they would have people hired, buy equipment, get geared up and possibly later the funds would not be available in the next few years. That seems to be the overriding reason why some States were reluctant to sign a contract in this area.

Senator SCHMITT. They are reluctant to spend their own funds?

Mr. HARDIN. Some States have spent their own funds. They are spending their funds primarily in still addressing the older equipment. The equipment more frequently used in the field, sir.

Senator SCHMITT. Do you believe it is a political problem in the States? Do you think the people are unwilling to go to their legislators and ask for funds for this? Is there a lack of public perception?

Mr. HARDIN. You are speaking of the budget area, I suppose.

I think probably the more difficult problem is to demonstrate with the effects of radiation being long term and difficult to justify from a dynamic impact, it may be that the difficulty there is of getting the moneys through the legislative system, being able to demonstrate the real effectiveness of the program.

I would not say it's a political problem. It's more one of trying to identify and make the legislature aware of what the problem is.

Senator SCHMITT. It sounds like politics. If we had a Federal program which established standards and regulations based on those standards, would you think it important to know the economic health, and other impacts associated with the imposition of the regulation? Obviously it's going to cost the taxpayer something to have the regulation in place, both directly through taxes and indirectly through higher consumer costs, commodity costs, or service costs.

Also, it might cause a slowdown in the rate at which X-rays would be used for diagnostic purposes, partly through fear of violating regulations and partly through just the existence of the regulations and the paperwork that would certainly come with it. Do you think such an impact should be part of the issuance of various rules?

Mr. HARDIN. Yes, sir, I do.

Senator SCHMITT. Impact analyses, I mean.

Mr. HARDIN. The total field of radiation protection, including the development of regulations, should always be the evaluation of the benefit versus the risk or hazards associated with whatever one is doing, as it relates to the cost of the regulation, yes, sir.

There should be a cost-risk-benefit analysis.

Senator SCHMITT. You are under contract to the FDA for certain activities in this area. Did I understand that correctly?

Mr. HARDIN. Yes, sir, that's correct.

Senator SCHMITT. Do you feel there has been sufficient analysis of the effect of your activities in this area? Do you see any secondary effects? Are people more reluctant to use X-rays, for example, for diagnostic work?

Mr. HARDIN. I think we have seen over the years much more concern in regard to the safe use of these machines as a result of the regulations. As far as the reluctance of applying radiation to the human body, I cannot say that I have seen that reluctance.

Senator SCHMITT. Do you get involved at all in looking at research equipment which produces radiation, both ionizing and nonionizing radiation?

Mr. HARDIN. No, sir.

Senator SCHMITT. Do you think this is an area which should have regulation?

Mr. HARDIN. In the area of research? Yes, sir, I think there are areas that still need research.

Senator SCHMITT. No, no. Do you think research equipment that utilizes radiation should be subjected to the rules and regulations which apply to industrial, medical, and other uses?

Mr. HARDIN. Oh, yes, sir, very definitely. They represent a potential exposure of the operator of such equipment.

Senator SCHMITT. Do you inspect such equipment in Kentucky?

Mr. HARDIN. Yes, sir.

Senator SCHMITT. What do you find relative to other uses? Are researchers more careful? Less careful? Is it all about the same?

Mr. HARDIN. This would have to be a personal comment. From some of my personal experiences, I think in general I have seen that researchers possibly may be, with radiation sources, less careful in some areas.

Senator SCHMITT. They are the ones that are supposed to know the most about it; is that correct?

Mr. HARDIN. That's corect.

Senator SCHMITT. That is interesting.

In your discussion of naturally occurring radioactive material, I didn't quite understand what you were proposing. Are you proposing rules and regulations which might be established on a Federal level to restrict our access to these naturally occurring materials?

Mr. HARDIN. Yes, sir. I would say this is one area where you have a great deal of concern among the States.

The Atomic Energy Act specifically covers byproduct, source of special nuclear materials.

These are materials that exclude naturally occurring materials like radium and machine artificially produced materials. That means there is a group of materials existing on which there is very little uniform control. Most States which have signed agreements with the Nuclear Regulatory Commission require the same responsibilities of control for that kind of material as required for byproduct source, and special nuclear materials.

There are only 25 agreement States. That means there are other States that do not control or at least have limited control. About five States do have a rather strong, active licensing and enforcement program for these kind of materials specifically, but there are other States that have very limited activity on the control of this kind of material. So what I was mentioning in the testimony was there may be a need for Federal legislation—I don't know, but at least concern in uniform control of these materials that do not fall under the Atomic Energy Act, such as radium. Radium represents possibly as much of a potential unnecessary exposure to the population as any of the materials under the act.

Senator SCHMITT. You are thinking of radium which is in the commercial sector being used as a material, not necessarily radium which is in the environment?

Mr. HARDIN. That's correct. Such as in medical practice, for example.

Senator SCHMITT. There are environments in this country and elsewhere in the world where there is abnormally high natrual radiation. We call it abnormal because it is not normal, such as certain granite bodies in New Hampshire and certain water supplies in New Mexico come through uranium mines. You weren't proposing, necessarily, that human access to these areas be restricted?

Mr. HARDIN. No, sir. I was primarily talking about these kinds of natural materials once they have been brought from the surface and are being used for some specific, either medical or industrial application.

Senator SCHMITT. Many of them are already at the surface.

Mr. HARDIN. Yes.

Senator SCHMITT. You said there is a need for national guidance and criteria as to what constitutes acceptable sites for the disposal of low-level radioactive waste.

We are finding in New Mexico, since we are being examined by both ERDA and by a private company as a possible waste disposal site, that it probably doesn't make too much difference whether there are "acceptable sites," that the public perception of radioactive wastes is the dominant factor, and the demonstration of technical acceptability has very little relation to the psychological acceptability. Do you have any experience in that either in Kentucky or your association? Do you have any recommendations as to what the country should do to solve this problem?

The radioactive waste problem is here; it exists. However, we don't really have an acceptable solution yet because the people of this country are not psychologically willing to tolerate the disposal of that waste near them.

In New Mexico, we recently had a poll which showed three-quarters of the people were amenable to having a nuclear powerplant, but three-quarters of the people didn't want the waste stored in New Mexico. This kind of dichotomy is one we are somehow going to have to find a way around.

Do you have any comments to the committee?

Mr. HARDIN. I am very much in agreement with the comments that you just made. The technical and public perception of acceptability are two different things. Some members of the conference have had similar experiences. In Kentucky, yes, very definitely, we had similar experiences from that viewpoint.

As to the resolution of that problem of public and technical acceptance, it appears the only answer is more and better education of the—in layman's terms, of what the technical issues are that we are talking about so the public can have sufficient information to evaluate and determine what we are talking about.

I think it boils down to that, trying to do a better job of informing them in the kinds of terms they can understand what we are talking about.

Senator SCHMITT. You work at the grassroots level. Do you feel there is any significant effort in education in the area? You have to start at the very first grade in order to build an understanding of what radioactivity is, what its dangers are, what its benefits are, and what its myths are.

Mr. HARDIN. The main public educational effort I am aware of is the program of the Nuclear Regulatory Commission through their—I believe it's called atoms for peace program that has been out for many years as an attempt to inform the public. I think specifically——

Senator SCHMITT. Excuse me for interrupting. Do you see any effect of that program in Kentucky?

Mr. HARDIN. Yes. I think I have observed people that are knowledgeable about the basic information of radiation.

As far as it relates directly to waste disposal, that still appears to be a problem that needs more addressing.

Senator SCHMITT. Do you have any suggestions on this problem in time to implement a national energy program which contains some proportion of nuclear power?

We are using radioactive materials in a wide variety of other areas. Even this low level waste you referred to is unacceptable to local communities in many areas.

Do we have an insoluble problem for the next 30 or 50 years? Do you have some suggestions of what we can do both at the State level and the Federal level in order to solve those problems? Regulations probably won't solve them.

Mr. HARDIN. That is a very difficult question you pose of how to properly address the area of public acceptance relative to technical acceptance.

Again, Senator, the only answer that I can at all see is the matter of public information, informing the public with some intensive, concentrated efforts at both the Federal and State level to better inform the public as to what we are talking about.

Once we have done that, hopefully, then, there will be a meshing of the technical acceptability with public acceptance. I do not have a suggestion of the exact type program to inform them. I think that is the only answer.

Senator SCHMITT. Unfortunately, Mr. Hardin, the irrational sides of this question—and they are irrational on both sides—would tend to look at that effort as unacceptable. That's another part of our dilemma. You start educating people on radioactivity to the point where in one perspective they become knowledgeable enough to accept it and to be able to live with it, but that is unacceptable to those who think we should not be using nuclear power at all in this country.

I am not stating my own preference. I am saying that's the kind of dilemma everybody is faced with. It is probably more of a dilemma at the State level than it is in Washington where you are dealing with the problem. You have to deal both with the people concerned about radioactivity and people who have yet to fully understand what radioactivity is.

It is unfortunate radioactivity got its introduction to our society, to the general population, through a disastrous event; namely, the atomic bomb.

Most new technology has entered the society in a rather benign way and we have grown up with it. Nuclear technology came in with a bang—pardon the expression.

I think it is going to take people like yourself, people like the Congress, people all over this country to figure out how to handle this new technological problem.

I know the committee appreciates your attempts to work in this area. I hope you will continue to communicate to us individually or as a committee any ideas you may have on how we can get around it. I frankly have yet to see the solution.

Mr. HARDIN. I share your—I suppose the proper word would be frustration in this area. We share it also at the State level. We do have the concern that you expressed at being able to communicate the acceptability of the technical area to the public. We share that, sir.

Senator SCHMITT. It is a very immediate question. The administration has decided to move on this energy policy, if they can get the Congress to agree, into increased emphasis on the use of light-water nuclear reactors with an increased production of nuclear waste, at a time when we have no acceptable national means of disposal of that waste.

So it is a very immediate problem, and if it is going to take 30 or 50 years to get public acceptability for the disposal of nuclear waste, then I don't see how we can implement that particular policy.

I have no further questions.

Did you have a comment?

Mr. HARDIN. I would just like to make a comment with respect to the disposal of both high-level and low-level waste.

In my opinion, the technology appears to be there for high-level through the information that I have read. As relates to low-level, I believe that the disposal of low-level radioactive waste—into the Earth when it is properly managed is an acceptable situation.

Senator SCHMITT. Technically, I agree with you. Psychologically, we don't have acceptability.

Thank you, sir.

Thank you, Mr. Chairman.

Senator STEVENSON. Mr. Hardin, you mentioned that the natural sources of radiation include phosphates.

Could you be a little more specific? What kind of phosphates? Phosphates in fertilizer?

Mr. HARDIN. Yes, sir.

I believe there are a couple of States that are particularly having an environmental problem with the phosphate industry of fertilizer.

I think there are some reports by the Environmental Protection Agency regarding that.

Senator STEVENSON. Is this in the mining of the phosphates?

Mr. HARDIN. I believe, sir, it is the storing—and I am really not that familiar with the problem directly—I believe it is the storing of the materials, some of the residue.

Again, I am not that familiar. I would recommend looking at the Environmental Protection Agency publications on this matter.

Senator SCHMITT. Mr. Chairman, uranium and thorium are concentrated in phosphates by geologic processes. For the most part now, it is not being extracted from those phosphates as they are translated into fertilizer. Fertilizer using phosphates will have a higher level of radioactivity than normal.

Senator STEVENSON. OSHA testified that it performed 28 inspections last year of industrial and commercial radiation equipment.

Do the States inspect in these environments, commercial, industrial?

Mr. HARDIN. Yes, sir. Some of the States have become—have an agreement with the Department of Labor in carrying out the inspection of the worker and workplace as it relates to those materials that fall under the Atomic Energy Act.

Most radiation control programs inspect a facility not only for protection of the public, but for protection of the worker.

Specifically, let's look at, let's say, a medical facility using X-rays, in which our inspectors look not only at the proper collimation of the machine for exposure to the patient, but also the protection of the worker behind a protective barrier, whether or not that person is or is not wearing a proper monitoring device.

In addition to that, we look at the structural wall as to whether or not it is providing protection to the surrounding environment.

Senator STEVENSON. All such inspections are under contract from the Federal Government?

Mr. HARDIN. No, sir. There are only a few of these that are under contract with the OSHA program throughout the country. I am speaking specifically of the radiation control agency which I am representing.

I believe there are only two of those that have signed or are participating in some manner with the OSHA program. The other States are not. They are not under contract with OSHA nor are they under contract—well, those other States do participate with the Federal Government, with the FDA on some of their inspections.

As it relates to OSHA, I believe there are only two programs I represent that are participating in OSHA.

Senator STEVENSON. What I am getting at is do the States on their own do what OSHA is not doing, inspecting work places?

For example, the airports where equipment is used to scan baggage?

Mr. HARDIN. Yes, sir. The majority of States do perform on their own, regardless of the contract with OSHA—the governments I am representing do perform inspections of places such as airports in which the baggage inspection units are used, inspections of industry where radioactive devices are used, or radioactive materials are used, that are not under the Atomic Energy Act.

Senator STEVENSON. Do you have an idea as to how many such workplace inspections were conducted last year?

Mr. HARDIN. Again, I don't have the number available to me. I believe it is in this report that I submitted, sir.

Senator STEVENSON. One last question.

You have recommended reductions in exposure to radiation from microwaves and radar, radio frequencies. Others have testified that there is no evidence to prove harmful effects from such sources.

Are you suggesting that there is such evidence? Why are you recommending reduced exposure?

Mr. HARDIN. No, sir, I certainly have no evidence of any biological effects. My comment there related to the fact that I believe this is an area in which there should be research done to assure there is no risk involved.

Senator STEVENSON. Thank you, sir.

Senator SCHMITT. Could I ask one followup question?

With respect to the burning of coal and other fossil fuel sources, does Kentucky intend to look at the radition exposure levels in the State as a consequence of the use of coal? Do any States have such plans?

Mr. HARDIN. Senator, we have been concerned about this and thought about it on several different occasions, of the type of study that may need to be done.

I will say it is very low on our priorities, currently, of radiation protection activities.

We are aware of that as being a potential exposure source and possibly may include that in some of our environmental work in the future. It is not in our immediate plans.

Senator SCHMITT. Do you know of any other State's plans? For example, I don't know the particular levels in Kentucky, but the lignites of the Dakotas are extremely high in uranium concentration.

Mr. HARDIN. I am not aware of other States' plans.

Senator SCHMITT. This is not something your conference has discussed?

Mr. HARDIN. No, sir.

Senator SCHMITT. Do you expect to bring it up on the agenda in the near future?

Mr. HARDIN. This, again, would be a personal comment. I would think so. I would think sources of natural radioactivity would be brought up in the near future.

Senator SCHMITT. Thank you.

Senator STEVENSON. Thank you, sir.

[The documents referred to follow:]

TASK FORCE REPORT ON BONDING AND PERPETUAL CARE OF NUCLEAR LICENSED ACTIVITIES, APRIL 5, 1976

PREFACE

There is a need for States and other territorial governments to protect themselves from financial burdening should a licensed nuclear facility not be able to decommission its activities upon termination of a license. This has occurred in several States already, and several States have taken action to acquire the necessary legislation to allow the authorization of bonding requirements on certain licensees. While this may protect the States and other government agencies from enormous financial loss, it should be realized that this mode of protection is no substitute for a viable radiation protection program.

Bonding is anticipated for use in the immediate decommissioning of the facility covering approximately a one year period. The trust funds or escrow accounts should be provided for use in long-term or perpetual care and maintenance programs. Insurance would be an alternative for third party protection should that be deemed necessary. Other alternatives were considered; however, they were not generally considered viable.

It was the feeling of the Task Force members that such financial protection is not deemed necessary in the majority of cases, and should be reviewed by each State as to the applicability of its circumstances and those of its licensees.

The appendices of this report include suggested legislation for licensee bonding and perpetual care trust funds and, also, changes to the suggested State regulations allowing the authorization of such bonding and perpetual care funds.

INTRODUCTION

The Task Force on "Bonding and Perpetual Care of Licensed Nuclear Activities" was established by the Executive Committee of the National Conference of Radiation Control Program Directors during June, 1974, in joint sponsorship with the Nuclear Regulatory Commission (NRC) and the Environmental Protection Agency (EPA), to investigate options available to States to assure licensee financial responsibility in the event of default. This Task Force is an outgrowth and extension of previous deliberations on radioactive waste management, and bonding and perpetual care requirements for shallow land burial sites. Because similar considerations relating to bonding requirements exist for all types of nuclear activities, the specific charge of the Task Force was to examine, in detail, the requirements for establishing bonding and perpetual care programs for all types of licensed nuclear activities, and to report the findings of the Task Force as guidelines to assist States in program development. Therefore, this report addresses only the options of bonding and perpetual care and is an update of the January 20, 1975 Task Force Report. Other mechanisms of financial responsibility such as a national indemnity fund, taxation, insurance, and financial qualifications were considered.

A previous examination of the status of bonding programs as they relate to licensed nuclear activities (excluding waste burial licensees) indicates only one State, New York, had instituted such a program; however, several States expressed concern in this area and are interested in the results and recommendations of the Task Force. During 1975, North Carolina and Arkansas passed bonding legislation. This increasing concern is attributable primarily to the possibility that a State might have to assume the responsibility for restoring a site where a licensed nuclear activity was conducted, to a radiologically safe condition and/or maintaining the site in perpetuity. Commensurate with the technological advances and proliferation of the nuclear industry, the complexity of the restoration process of any licensed activity will, in all probability, require financial resources not available to the State. Since the public health and safety must not be compromised, it becomes necessary for the State to initiate actions to insure that its public responsibilities are met. While other concepts of assuring financial responsibility as a prerequisite for licensure are available and used, (e.g., the financial responsibility concept used by the NRC) it was concluded that the bonding and trust fund concept would satisfy many of the situations that an individual State may encounter and is, in the majority of cases, the method of choice.

The objective of the Task Force effort was to assemble into a single document the guidance necessary for State and Federal officials to develop bonding and perpetual care programs. Specific work topics were identified by the Task Force and in formulating the guidance, the approach taken was as follows:

To determine, in general classes, those licensed activities which may require consideration for bonding and/or perpetual care;

To identify the legislative authority necessary to establish bonding and perpetual care programs;

To develop monetary ranges of performance bonds and perpetual care trust funds; and

To identify administrative areas to be considered by the State in developing, implementing and maintaining bonding and perpetual care programs.

Ensuing portions of this report discuss each identified topic in detail, and in some cases, (e.g., legislative requirements) offer several alternatives and examples that may be considered. While attempting to suggest monetary ranges for performances bonds and trust funds, the Task Force found it difficult to etablish an exact cost estimate for any given class because of the variance of basic costs, as well as the differing restoration/maintenance requirements peculiar to the class. Wide monetary ranges are presented and are considered by the Task Force to be representative of minimum and maximum costs that may be encountered; however, each State must, using the identified parameters, evaluate the financial requirements of a given class by an individual cost analysis.

Finally, the Task Force has identified potential issues which should be considered prior to the adoption and implementation of any bonding or personal care program. Primarily, the issues relate to the following:

Licensing and regulatory jurisdiction over decommissioned facilities originally licensed by the NRC;

Difficulties that may be encountered by States if the NRC fails to adopt similar programs;

Reciprocal recognition of bonds between States and between States and the NRC;

Individual variability between States; and

Restricted availability of large dollar-amount bonds due to the collateral requirements.

Part IV, Recommendations, attempts to resolve these issues and also contains recommendations of the Task Force for a systematic approach to bonding/perpetual care programs.

The Western Interstate Nuclear Board is preparing a report of a similar nature on uranium mills and that report should provide additional information on this subject.

PART I PROBLEM DEFINITION

To investigate bonding and trust funds as a mechanism available to the State or Federal agency having regulatory jurisdiction over the activities of certain classes of users of radioactive materials to assure that sufficient funds will be available to decontaminate or decommission a licensed activity. The user classes identified are:

1. Major processors of radioactive material (not including special nuclear materials sufficient to form a critical mass);
2. Waste handling licensees;
3. Ore refineries—mills;
4. Former NRC licensed facilities which utilized special nuclear materials sufficient to form a critical mass; and
5. Other specific licensees.

The establishment of a financial responsibility program cannot be substituted for a sound, well-executed regulatory program, but employed only as a contingency in the event of licensee default. The Task Force has not endorsed the need for bonding of all licensees but if deemed necessary, the suggested legislation provides the mechanisms for such a program. Bonding and trust fund requirements should be instituted to assure the availability of money needed for the closing of nuclear activities and/or bonding the performance of a licensee relative to the protection of the public health and safety. Bonds would provide immediate, short-term financial resources to control and/or eliminate the radiological hazard; while trust funds would provide financial resources for long-term maintenance and surveillance costs if complete removal of the hazard is not accomplished.

For purposes of this report, the term "bond" means a contractual obligation in writing binding the obligor (licensee) to observe the provisions of the Laws, Rules and Regulations, Special Conditions, and Orders governing the issuance of the license, and in failure to follow such, to pay a sum of money to the obligee (agency) and permit the obligee or its designee to enter the property of the obligor for purposes of decontamination, with the stipulation to the effect that on performance of a certain condition (i.e., satisfactory decontamination by the obligor) the obligation shall be void. Used in this context, an acceptable bond may be any of the following:

1. A bond issued by a fidelity or surety company, if available;
2. A personal bond secured by collateral;
3. A "letter of credit" issued by a recognized financial institution; and
4. A cash bond posted by the licensee.

Bonds of this type are usually renewed on an annual basis and contain a short-term (30 days) cancellation clause by the surety which may require immediate action by the Agency.

In the context of this report, a "trust fund" means a legally established fund or aggregate of assets dedicated by the Trustor for the specified purpose of underwriting all costs of maintenance and surveillance of sites which pose radiation hazards or require continuing care; and which the beneficiary can spend under terms of the trust agreement only to effect the specified purposes.

I. MAJOR PROCESSORS

A major processor is considered to be a user processing, handling, or manufacturing radioactive materials exceeding Type A quantities as unsealed sources or material or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, radiographers or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4.

A. NEED

A radioactive material user of this size usually will initially have an adequate financial base and can sustain significant expenses in decontaminating equipment or facilities and providing for the annual maintenance and surveillance of the site as required. In time, the company's financial resources tend to become limited if it cannot maintain its market position. In the event of a contaminating incident at the plant, the company may no longer have the financal resources to adequately correct the situation. The bond would provide funds to accomplish that task.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

Setting the amount of the bond involves a complex evaluation of the licensee's activities being bonded. Factors to be considered are:

1. The amount, isotope, and chemical form of radioactive materials involved;
2. Facility structural factors, for example:
   - a. Types of ventilation;
   - b. Isolation capability;
   - c. Double containment and building design;
   - d. Above or below ground operations; and
   - e. Fencing or other access control;
3. Environmental factors, for example:
   - a. Water table;
   - b. Meteorology;
   - c. Migration rate (soil);
   - d. Surrounding water and land use; and
   - e. Access to facilities;
4. Costs of decontaminating rooms, equipment, etc.;
5. Costs of soil removal and disposal;
6. Costs of debris removal and disposal; and
7. Annual maintenance and monitoring costs.

C. ESTIMATED COST RANGE: $1,000,000 TO $5,000,000

After reviewing a proposed decommissioning of a major processor and discussing the factors to be considered in estimating restoration costs, the Task Force selected the estimated range as being representative of costs that may be incurred. Appendix A contains a summary of the estimate of a recent decommissioning of a major processor. The upper bound of the estimate includes complete removal.

II. WASTE HANDLING LICENSES

Waste handling licensees include organizations which hold radioactive wastes for later disposal and those which actually dispose of the wastes. Storage or holding of wastes generated solely by the storing organization would not be included. Those licensees which process the wastes prior to disposal should be considered major processors if the quantities of radioactive material which they are authorized to possess met the amounts described for that class.

A. NEED

The need for the bonding of waste handling license activities has been discussed in a previously developed statement by the National Conference of Radiation Control Program Directors and is Appendix B to this report. For those sites which serve as a temporary storage for wastes, the need as given for major processors above is appropriate. In addition, one should be aware that generally these companies do not have the equipment or mortgage base available should funds be needed.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

Setting the amount of the bond for a waste burial site has been previously developed by the National Conference of Radiation Control Program Directors and is also included in Appendix B to this report. It should be stressed that the bond established for this type of licensee is for basically three things:

1. Burial of any wastes not buried by the operator;
2. Payment of any monies due the perpetual care fund; and
3. Preparation of the site for a new operator or for decommissioning.

Setting the amount of the bond for other waste handling licensees generally follows the factors considered for major processors. One should recognize that in many cases these licensees do nothing but handle Department of Transportation approved packages, thereby reducing the hazard potential.

C. ESTIMATED COST RANGE: $50,000 TO $500,000

Included in estimating these amounts are the decommissioning costs, funds due the perpetual care trust fund at the time of default or forfeiture and the maintenance and monitoring of the site for at least one year to permit possible site reactivation, if desirable. Perpetual care trust fund inclusion plays an important role in arriving at such a figure. A "point-of-no-return" would be identified at which time complete removal could no longer be economically considered in light of the health benefits involved.

III. ORE REFINERIES—MILLS

Ore refineries include all processors of a radioactive material ore. The product of this processing should not exceed the low specific activity definition given in 10 CFR 71.4(g). The waste product of the processing is usually radioactive "tails." Those processors handling radioactive materials concentrations above the low specific activity levels are considered major processors if the quantities possessed otherwise meet the amounts described for that class.

A. NEED

The need for bonding is best described by the need for continual control of the "tailing pond," or "tailing pile," or other retention system. The company operating the facility is subject to the same adverse financial conditions as described for major processors. In addition, the "tails" are likely to be considered disposed of and therefore may require extremely long term care.

B. FACTORS TO CONSIDER IN SETTING THE AMOUNT OF A BOND

The factors used in setting the amount of a bond for a major processor also apply to this class; however, certain modifying factors should be considered. These are:

1. Any contamination is low specific activity; therefore, decontamination of facilities and equipment is easier and cheaper.
2. The long term care requirements of the "tailing pond," "tailing pile" or other retention system, may require the establishment of a perpetual care fund. Appendix B discusses the establishment of a perpetual care fund and this Task Force recommends its consideration.

C. ESTIMATED COST RANGE: $500,000 TO $5,000,000

The cost range is for licensees with tailing piles and without need for relocation of the pile. A major consideration is the amount required for stabilization of the pile in connection with decommissioning of the facility. If a mill tailings pile, or other waste retention system, is not associated with the authorized use, appropriate downward adjustments of these figures would be required.

IV. FORMER NRC LICENSED FACILITIES

These facilities include all nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plats, and critical experimental facilities.

A. NEED

Fome NRC licensed facilities may be divided into two classes: (a) those with large inventories of mixed fission products and some transuranics; and (b) those with no transuranics and small inventories of mixed fission products. In all cases, long half-life materials are involved, and therefore the contamination must be removed or long term monitoring and perpetual care instituted. Otherwise, the need is the same as for a major processor.

B. FACTORS TO BE CONSIDERED IN SETTING THE AMOUNT OF A BOND

The factors to be considered in setting the amount of bond vary according to facility type. Generally, the considerations of a major processor apply, but additional factors should be taken into account for each type of production or utilization facility. These are:

1. Nuclear Reactors—The current NRC regulations provide for a detailed review of an applicant's financial resources to assure that the applicant can safety operate a nuclear power plant. Additionally, while in operation, the nuclear power plant represents a major asset to the operator; however, after the plant is decommissioned or shut down, it becomes a liability. It appears that the former nuclear reactor licensee will be under strong economic incentive to transfer title to another entity and thereby reduce the long term liability. It is recommended that any person holding an NRC "possession only" license for a decommissioned nuclear reactor be required, at the very least, to post a bond sufficient to provide a perpetual care fund covering the monitoring and maintenance costs for the liability.
2. Nuclear Fuel Reprocessing Plants—The considerations of this type of facility are the same as for a nuclear reactor.
3. Uranium Enrichment Plants—The considerations for this type of facility are the same as for major processors.
4. Critical Experiments Facilities—Those in low power range (<10 watts) have low fission product inventories and have the same considerations as major processors. Those in the high power range (>10 watts) should be considered, for bonding purposes, similar to nuclear reactors.

C. ESTIMATED COST RANGE: $50,000 TO $500,000

1. Nuclear Reactors—$50,000 to $500,000

   The estimated bonding costs for nuclear reactors depend on which of the four alternatives provided in the Regulatory Guide 1.86 "Termination of Operating Licenses for Nuclear Reactors" are used, the size of the reactor and the decontamination problems associated. Residual radiation levels on sites for unrestricted use should be as low as practicable but in any case far below those specified in Table 1 of the Guide. The estimated cost range does not include those decommissioning costs associated with termination of the NRC operating license but only includes those costs which may be incurred to provide annual maintenance.

The cost of decommissioning a two-reactor facility has been estimated at approximately $2,000,000, with a $100,000 annual maintenance cost. A complete removal of all radioactive material has been estimated at $75,000,000.

2. Other Former NRC Licensed Facilities—$50,000 to $500,000.
3. Critical Experimental Facilities—$10,000 to $100,000.

V. OTHER SPECIFIC LICENSES

A. NEED

Most of the users of radioactive material present a low potential for a major problem. For example, if a user of a gauge containing radioactive material declares bankruptcy, shipping the gauge to a licensed recipient is all that is required. Similarly, small research programs, nuclear medicine programs, industrial radiography, etc. each represent a fairly low cost decontamination problem. One should note that many programs start in this class and grow into another.

B. ESTIMATED COST RANGE: $1,000 (10,000) TO $500,000

Except for those licensees exempt or excluded from the recommended bonding requirements, an appropriate "across the board" (one amount for the entire class of licensees) application of a bond amount would be between $1,000 and $10,000 as a minimum. A normal maximum for this class could approximate $500,000. Complete removal of radioactive material is anticipated.

In providing guidance for perpetual care trust funds, the Task Force recommends that for only two cases—waste handling licensees and source material ore milling operations—should perpetual care funding be initially provided. Perpetual care funding may also be required for formerly AEC or NRC licensed facilities. All other sites would be expected to be decontaminated to a level as low as practicable to protect the public health and safety. This policy would preclude proliferation of perpetual sites throughout the nation. The interest on the amount required to be maintained in the trust fund should provide an annual amount equal to the anticipated costs of perpetual care. Anticipated costs of perpetual care for both waste handling facility and ore refinery sites would range between $50,000 to $250,000 per year. A trust fund principal of $3,000,000 will yield approximately $150,000 in interest annually, according to the 1974 National Conference Workshop No. 3 Report. The Report of Workshop No. 3 contains information as to the items of concern in providing perpetual care.

Bonding provides for the infrequent case in which a licensee is willing or unable to appropriately provide for decommissioning and the monies due to the perpetual care fund for the site. Perpetual care trust funds allow for the continuation of appropriate management of the site into the foreseeable future. It should be noted that bonding and perpetual care trust fund provisions do not provide for third party protection. While the Task Force was of the opinion that the licensing agency was under no obligation to require such insurance, it may be advisable to identify if licensees have provided for this matter.

PART II AUTHORITY

The purpose of this part is to discuss (1) the necessary legislative authority for requiring licensees to assure their financial responsibility through the posting of bonds and establishment of perpetual care trust funds; and (2) the requisites of performance bonds and trust funds. The Task Force is aware that some Agreement States have already determined that specified legislation to authorize bonding and trust funds of their licensees is not required, since their legal counsels have determined that the existing legislation establishing their agency provides sufficient authority for establishment of these requirements. However, the Task Force believes that most States will require an amendment to existing legislation in order to specifically grant the State the authority to require bonds and trust funds. Counsel in at least one State has stated that although existing law does not prohibit the imposition of bonds, the State would be in a stronger position if the legislation specifically granted the authority for the requirement of bonds.

Each State should investigate with its own legal counsel which of the two following approaches is appropriate for requiring bonds and establishing perpetual care funding within the State.

I. States where existing legislation is deemed adequate

For those States where legal counsel deems that the existing legislation provides sufficient statutory authority for the requirements of bonds and establishing perpetual care funding, the following criteria should be met:

A. The legislation should provide sufficient authority to establish the bonding and perpetual care fund requirement.

B. The authority to establish bonds should be broad enough to require bonds of adequate types and amounts.

C. The authority to establish perpetual care funding should be broad enough to cover the amounts needed for long term maintenance and surveillance of the site.

D. The legislation should specify where the proceeds of forfeited bonds are to be deposited and how they can be used.

E. The legislation should state any exclusions or exemptions from bonding and perpetual care requirements which may be deemed appropriate (e.g., State and local agencies) and should have a provision that additional exemptions by types of licensees may be provided by the State regulatory agency.

Where the State deems that the existing legislation is appropriate and meets the criteria as stated above, its rules and regulations implementing the statutory authority should be amended and, as a minimum, provide for the following:

A. A definition of what constitutes an acceptable bond (this may be defined within the state statute).

B. An effective date of the rule or regulation allowing at least a 90-day period for implementation.

C. A specific description of how the forfeited funds may be used; e.g., cleanup of contaminated facilities, etc.

D. A mechanism for administering the bonding and perpetual care requirements for existing State licenses.

E. A requirement that the bond be issued and in the possession of the State regulatory authority at the time the license is issued.

F. A requirement that the perpetual care fund be established prior to the time the license is issued.

G. A requirement for the provision of adequate bonding by range of dollar amount and a statement that all exemptions may be based on possession limit, form or other category deemed appropriate.

Appendix C "Proposed Changes to the Suggested State Regulations" contains an example of the language necessary to amend Section C.25 to include the above requirements.

II. States where it is deemed that amendment of existing statutes is necessary to authorize imposition of bonding and perpetual care funding requirements for licensees

All of the criteria for legislation and provisions that should be incorporated in the State rules and regulations, as discussed in the previous section, should be followed in conjunction with the enactment of amendment of existing State statutes to authorize bonding. Suggested language for such amendatory legislation is contained in Appendix D "Suggested Legislation for Licensee Bonding and Perpetual Care Trust Funds."

III. Other considerations

In addition to the legislative authority necessary to establish bonds and trust funds, each State regulatory agency should determine clearly what constitutes a legal bond or trust fund within the State. In the case of establishment of trust funds, the ownership of the land must be clearly defined. It is the Task Force's opinion that although bonds should be required of most specific licensees, trust funds for perpetual care are only necessary for waste handling licensees and ore refinery activities where tailings piles are generated. However, it was also considered that trust funds for perpetual care should probably be established for any former NRC licensed facility when it is decommissioned and when there is a likelihood that it will become a permanent disposal site as opposed to total dismantling of the facility or decontamination. Most States already have requirements for trust funds for waste handling sites, but these are all located on State owned property. In the case of ore refinery sites and former NRC licensed facilities, they are normally located on private property and thus the problem of ownership of the land must be clearly resolved.

PART III ADMINISTRATIVE

It should be recognized by the agency that implementation of a bonding/perpetual care program is no small undertaking either for the licensee or the agency. It is most important that the bond be in effect prior to issuance of the license, which is basic to the concept of any resultant legal procedure and is the only way adequate protection can be provided. Therefore, it should be a condition of issuing all new licenses that the bond in effect prior to issuance of the license. Assuming legislation or other legal authority authorizes the establishment of bonding/perpetual care programs, administrative procedures must be developed and provided to implement the program. Because bonds will frequently be a very significant cost item to some licensees, bonding requirements should be clearly delineated in the regulations governing the issuance of licenses by the agency.

Imposition of a bond upon all existing licensees should be accomplished by requiring all existing licensees to obtain a suitable bond as a condition of the license within a specified period of time or making a bond a condition of licensure at the time of renewal. In either case, adequate warning and necessary information as to the specific requirements of the bond should be provided to all licensees. Each licensee should be notified in writing as to the range of bond amount required. The time permitted should recognize the economic, legal, and administrative impact upon the licensee and the agency. Consideration should be made of the establishment of a priority system for administering the requirements of existing licensees. The letter should also provide information as to the availability of such bonds within the agency's jurisdictional area and should be clear of any implication of "conflict of interest."

It should be reemphasized that considerable staff time will be required of the Agency to implement this facet of its program with a lesser requirement for its maintenance. It is estimated that any agency having 500 existing licenses and which imposed a standard bond amount upon all such licenses, would require 1.5 to 2.0 man-years of technical staff for implementation and require 0.3 man-years effort for maintenance. It would also require 0.5 man-years clerical and secretarial staff time. In addition to staff time, all other costs for agencies such as legal services shoudl be considered if there is not a legal staff available to the agency.

Adequate written guidelines for staff use and implementation of the program should be provided. These should include procedures for the following:

1. Basic administrative processing of the bonding requirements in concert with existing administrative procedures of the agency and in accordance with a possible priority system.
2. Basic legal processing in accordance with laws governing such legal instruments.
3. Specific guidelines to be used in determining the amount of the bond required for each specific license.
4. Periodic review of bonding requirement as a normal license review and/or amendment procedure.
5. Periodic review at the expiration of the bond or licenses.
6. Provision for an adjustment of bond amount for inflation.
7. Implement a safe depository for the bonds.
8. Provision of written procedures to be implemented in the event of failure to perform adequately by the licensee requiring forfeiture of the bond.
9. Provision for the transfer of funds to the agency.
10. Provision for definition of proper use of bonding funds made available to the agency by forfeiture, including possible establishment of a trust fund for perpetual care.
11. Provision of written procedures for implementation of corrective action by the agency.
12. Provision of procedures for the establishment of a trust fund for perpetual care of the facility if need develops.

One method of assuring that an adequate period of binding is in efiect at all times may be to initially require a twelve month bond and further require that an additional six month premium be paid at the end of each six month period thereafter. This requirement would provide the agency with six months of lead time to take any necessary action against a licensee who refuses to obtain further bonding.

PART IV RECOMMENDATIONS

The Task Force has concluded that a financial responsibility review system, as a prerequisite for certain licensees to possess and use radioactive material, should be instituted at both the State and Federal level. Bonding and perpetual care trust funds can, to a limited extent, serve as an integral part of the system but caution should be exercised in relying totally on bonding programs because of the possible restricted availability of large dollar amount bonds. The Task Force found surety companies reluctant to issue assurance bonds in excess of $1,000,000 unless secured by 100 percent collateral; nevertheless, it is the position of the Task Force that bonding and perpetual care programs be considered as the principal option of the total financial responsibility assurance. Accordingly, the Task Force submits the following for consideration:

1. It is recommended that the Executive Committee of the Conference accept this report for presentation to the Conference and implementation of the recommendations as appropriate.
2. Further, other alternatives to bonding and perpetual care trust funds have been considered and are generally not viable. It is recommended that the Task Force be discontinued and that the Executive Committee establish a mechanism for periodically assessing the viability of programs instituted and the need for additional effort in this area.
3. Further, it is recommended that each State consider the adoption of a bonding and perpetual care trust fund program as a portion of the total financial responsibility review system.
4. Further, it is recommended that Appendices C and D of the report be submitted to Task Force No. 6 for inclusion into the Council of State Governments Suggested State Regulations and Legislation.
5. Further, it is recommended that the NRC consider the adoption of a similar financial responsibility review system for certain licensees that would include, as necessary, a bonding and perpetual care trust fund program.
6. Further, it is recommended that the Federal Government establish a policy providing for financial and technical assistance in taking remedial measures at the commercial radioactive waste disposal sites. (In concurrence with the GAO report "Improvements Needed in the Land Disposal of Radioactive Wastes—A Problem of Centuries," dated January 12, 1976.) Studies and remedial actions to be performed at ERDA radioactive waste disposal facilities should be accomplished with State radiological health program involvement.

APPENDIX A

SUMMARY OF THE COST ESTIMATE TO DECONTAMINATE THE AMERICAN NUCLEAR COMPANY

Excerpts from "A Study of Radioactive Contamination at the American Nuclear Company Plant," Oak Ridge National Laboratory, November 1, 1973

A facility with a "hot cell" operation and a storage well containing 50,000 curies of cobalt-60 and 18,000 curies of cesium-137 requires extensive decontamination. The facility has contamination throughout and has soil contamination due to waste treatment problems. The removal of the cobalt and cesium from storage, the welding shut of some doors, and decontaminating and securing the building to where the potential of public contamination is small would cost an estimated $145,000. To remove soil and decontaminate the building to the extent that unrestricted use of the property may be permitted was estimated to cost $1,000,000 to $2,000,000. One should note that the $145,000 would not cover the annual public cost to monitor or maintain the facility.

The estimated costs are as follows:

$90, 000	decontaminate "hot cell"
33, 000	decontaminate office
22, 000	excavate hottest earth
$145, 000	Total
(18, 000	additional for fence around 15 acres.)

APPENDIX B

1974 NATIONAL CONFERENCE ON RADIATION CONTROL WORKSHOP NO. 3 REPORT

What are the bonding and perpetual care requirements for waste burial sites?

Scope: This workshop is to consider the bonding and perpetual care requirements of State-licensed shallow land burial sites used for the disposal of radioactive wastes. Of particular concern is the problem of assuring sufficient funding to maintain, in perpetuity, the integrity and security of a waste burial site, including perhaps surveillance and monitoring. Similarly, the question of bonding to assure acceptable performance by the operator or to provide adequate operational funds in case of default by the operator needs to be explored.

PREFACE

As the scope of this workshop represents an extension of similar past considerations of the Conference's Task Force on Radioactive Waste Management, the following report should be appended to the April 24, 1974 report of that Task Force.

Workshop No. 3 recommends that the Executive Committee adopt the following as Conference recommendations:

"The State should assure that:

1. A performance bond is posted by the burial site operator payable to the State agency having the responsibility for closing and maintaining the site in the event of default or other inability of the operator to meet the requirements of the regulatory authority or contract obligations. Such performance bond should be adequate to cover the following costs:

   a. The decommissioning of the site so as to require minimum maintenance.

   b. The payment of any funds due the perpetual care trust fund at the time of default.

   c. The maintenance and monitoring of the site for at least one year to permit possible site reactivation, if desired.

   Generally, this performance bond should be between $50,000 and $500,000, depending on site characteristics.

2. A perpetual care trust fund is legally established which should draw interest adequate to pay the costs of monitoring and maintaining the decommissioned site. The perpetual care trust fund should be identified and limited to the monitoring, maintenance, and other perpetual care at the radioactive waste burial site. The estimated costs of monitoring and maintaining the decommissioned site should be re-evaluated periodically, but not exceeding five years and the contract with the operator renegotiated as needed.

   Items to be considered in determining the perpetual care trust funds are:

   a. Surveillance, including salaries, travel expenses, instrument maintenance, overhead, and well drilling.

   b. Maintenance of site, including labor, salaries, overhead, special equipment (evaporators, etc.), fence repair, and erosion control.

   c. Contingency fund, including potential protective actions to prevent unacceptable release of waste materials from the site, including land acquisition, and blocking procedures."

Generally, the annual interest from the perpetual care trust fund should be between $50,000 and $250,000 depending on site characteristics. $3,000,000 in a trust fund will yield approximately $150,000 in interest annually.

The perpetual care trust fund is the crux of the legal and financial matters to be considered. For the purposes of licensing, once radioactive material is buried it is no longer subject to the license possession limit. This is based on the concept that there is no intent to remove radioactive waste from the burial site and is the basis for the State assuming the responsibility for any costs of monitoring and maintaining the site after decommissioning. Prior to decommissioning, the license should be conditioned to require the operator to perform an adequate monitoring and maintenance program of the burial site, to both protect the public health and safety and to minimize future maintenance costs.

Once the radioactive wastes are buried in accordance with license conditions, any disinterment of the solid wastes resulting from changes in State or Federal regulations would be at State or Federal expense. Any disinterment of the solid wastes should only be performed under conditions specifically approved by the regulatory agency.

3. Nuclear Liability Insurance is posted in the amount of at least $1,000,000.

Regulatory authorities and other interested agencies should apply the above criteria to all future burial sites. Presently operating sites should meet the above criteria at the next license renewal and/or contract renewal.

Co-Chairmen: Aubrey Godwin, Alabama, Michael Christie, Idaho.

APPENDIX C

SUGGESTED CHANGES TO THE SUGGESTED STATE REGULATIONS

Sec. A.2 Definitions

* * *

(bb) "Major Processor" means a user processing, handling, or manufacturing radioactive materials exceeding Type A quantities as unsealed sources or material or exceeding four (4) times Type B quantitie as unsealed, sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4

(bc) "Waste Handling Licensees" means persons who hold radioactive wastes for disposal and/or those who actually dispose of radioactive wastes.

(bd) "Ore Refineries" means all processors of a radioactive material ore.

(be) "Former U.S. Atomic Energy Commission (EC) or U.S. Nuclear Regulatory Commission (NRC) Licensed Facilities" means nuclear reactors, or nuclear fuel reprocessing plants; or uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

Sec. C.25 General Requirements for the Issuance of Specific Licenses

* * *

(a) * * *

(b) * * *

(c) * * *

(d) * * *

(e) Bonding Requirements

(1) Pursuant to (cite provisions of the Act), and except as otherwise provided, a bond made payable to the (Director of the Agency) and in the amount specified in paragraph (e)(4) shall be posted to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the Act and these regulations.

(2) The bond required in paragraph (e)(1) shall be received by the (Agency) prior to issuance of a license. An acceptable bond is ———.

(3) Amendments to licenses in effect on (the effective date of this regulation) may be issued providing that the required bond is received by the (Agency) within 90 days after (the effective date of this paragraph (e)).

(4) The following specific licensees are required to post a bond within the range of amounts specified:

(i) Major Processors ($100,000–$5,000,000)

(ii) Waste Handling Licensees ($50,000–$500,000)

(iii) Ore Refineries—Mills, with associated trailings piles ($500,000–$5,000,000)

(iv) Formerly AEC or NRC Licensed Facilities ($50,000–$500,000)

(v) All others except persons exempt pursuant to paragraph (e)(5) (Minimum of $1,000–$10,000 to $500,000.) (A minimum bond shall be established if in the opinion of legal counsel it is necessary to meet State constitutional provisions on equality.)

(5) The following persons are exempt from the requirements of paragraph (e)(1) (A minimum bond shall be established if in the opinion of legal counsel it is necessary to meet State constitutional provisions on equality):

(i) All State, local, or other governmental agencies unless they fall in subparagraphs (e)(4)(ii) or (iii) above,

(ii) Persons authorized to possess no more than 1,000 times the quantity specified in Schedule B, Exempt Quantities, or combinations of radioactive materials listed therein as given in Note 1, Schedule B.

(iii) Hydrogen-3 contained as hydrogen gas in a sealed source,

(iv) Radioactive noble gases in sealed sources with no radioactive daughter product with half life greater than 30 days,

(v) Reserved (There may be others a State wishes to consider)

(vi) Reserved (There may be others a State wishes to consider).

(6) This paragraph (e) becomes effective on ——— (90 days after enactment of appropriate legislation or such time period as prescribed by the State Administrative Procedures Act).

(f) Perpetual Care Requirements

(1) Pursuant to (cite provisions of the Act), and as otherwise provided, a perpetual care trust fund shall be established prior to the issuance of a license.

(2) The following specific licensees are required to provide perpetual care funding. (Perpetual care funding may also be required for formerly ACE or NRC licensed facilities.)

(i) Waste Handling Licensees

(ii) Ore Refineries

Schedule B, Note 1

For purposes of Section C.25 (e) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed one (i.e., unity).

Example:

Amt. of Isotope A possessed

Example:

$$\frac{\text{Amount of isotope A possessed}}{1{,}000\times\text{schedule B quantity for isotope A}}+\frac{\text{Amount of isotope B possessed}}{1{,}000\times\text{schedule B quantity for isotope B}}\leq 1$$

Appendix D

SUGGESTED LEGISLATION FOR LICENSEE BONDING AND PERPETUAL CARE TRUST FUNDS

Section ———, Bonds

(a) The (Director of the Agency) or his duly authorized representative shall require the posting of a bond by licensees to provide funds in the event of abandonment, default, or other inability of the licensee to meet the requirements of the (Agency). The (Agency) is hereby authorized to establish bonding requirements by classes of licensee and by range of monetary amounts. In establishing such requirements, the (Agency) shall give consideration to the potential for contamination injury, cost of disposal, and reclamation of the property.

(b) All bonds forfeited shall be paid to the (Director of the Agency) for deposit in a special fund by the (State Treasury) called the (Radiation Reclamation Fund). All monies in such Fund are hereby appropriated and may be expended by (Director of the Agency) as necessary to assure the protection of the public health and safety. Monies in this fund shall not be used for normal operating expenses of the Agency.

(c) A bond deemed acceptable in (name of State) shall be a bond issued by a fidelity or surety company authorized to do business in (name of State), a personal bond secured by such collateral as the (Director of the Agency) deems satisfactory, cash bond, or a letter of credit. (Acceptable bonds may be spelled out in existing State laws and this provision should be consistent with those laws.)

(d) All State, local, or other governmental agencies, or subdivisions thereof shall be exempt from the requirements of this Section ———. The (Director of the Agency) is authorized to exempt classes of licensees from the requirements of this Section when a finding is made that such exemption will not result in a significant risk to the public health and safety. (If a State constitutional problem exists, Section C.25 (e) (5) must be revised accordingly.)

Section ———, Perpetual Care Trust Funds

(a) The (Director of the Agency) or his duly authorized representative shall require a licensee to deposit funds, on an (annual, semi-annual, quarterly) basis, in a trust fund when it is deemed there is a reasonable possibility that the licensed activity may eventually cease to operate although still containing, or have associated with the site at which the licensed activity was conducted, radioactive material which will require maintenance, surveillance or other care on a continuing and perpetual basis.

(b) In order to provide for the proper care and surveillance of sites subject to paragraph (a) of this Section, the State may acquire by gift or transfer from another government agency or private person, any and all lands, building, and grounds necessary to fulfill the purposes of this Section. Any such gift or transfer is subject to approval and acceptance by the State.

(c) The (Department) may by lease or license with any person provide for the operation of a site subject to this Section for the purpose of carrying out the provisions of this Act. Any lessee or licensee, including all State, local, or other governmental agencies or subdivisions thereof, operating under the provision of this paragraph (c) shall be subject to (Section ———, Bond).

(d) The funds required by paragraph (a) of this Section shall be established at such rate that interest on the sum of all funds reasonably anticipated as payable shall provide an annual amount equal to the anticipated reasonable costs necessary to maintain, monitor and otherwise supervise and care for the lands and facilities as required in the interest of public health and safety. In arriving at the rate of funds to be deposited, the (Department) shall consider the nature of the licensed material, size and type of activity, estimated future receipts and estimated future expenses of maintenance, monitoring, and supervision.

(e) All funds accrued as interest monies deposited in the perpetual care trust funds are hereby appropriated and may be expended by the Director to monitor and maintain the site as required to protect the public health and safety on a continuing and perpetual basis.

Recognizing the uncertainty of the existence of a person or corporation in perpetuity, and that ultimate responsibility to protect the public health and safety must be reposed in a solvent government, without regard to the existence of any particular agency or department thereof, all lands, buildings, and grounds acquired by the State under paragraph (b) of this Section shall be owned in fee simple absolute by the State and dedicated in perpetuity to the purposes stated in paragraph (b). All radioactive material received at such site and located therein at time of acquisition of ownership by the State becomes the property of the State.

(g) In the event a person, licensed by any governmental agency other than the State of (name of State), desires to transfer a site to the State for the purpose of administering or providing perpetual care, a lump sum deposit shall be made to a trust fund. The amount of such deposit shall be determined by the (Director of the Agency) taking into consideration the factors stated in paragraph (d) of this section.

Section ———.

(a) The provisions of this Act are severable and if any part of the Act is declared invalid or unconstitutional, such declaration shall not affect the validity of the part which remains.

(b) The Act is cumulative and is intended to supplement existing laws, and no part shall be construed to repeal any existing law specifically enacted for the protection of public health and safety.

(c) The provisions of this Act shall take effect 90 days after its passage and approval by the Governor of its otherwise becoming a law.

PREHEARING QUESTIONS AND RESPONSES OF THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

RESPONSE

Question 1. Please review your current programs and identify for the Committee the issues which you perceive are in need of resolution. This discussion may include those issues which appear to be of immediate consumer concern or those issues which are relevant to a clarification of federal agency responsibility. They may include your views as to needed revisions in existing legislation, initiation of research, education and training, state and federal cooperation, transportation, materials handling, disaster response, inspection or certification of devices and other similar issues.

Answer. To properly review the current programs of the Conference of Radiation Control Program Directors, and to identify the issues which need resolution, a brief description of the Conference may be helpful. The Conference of Radiation Control Program Directors (CRCPD) is an organization whose membership is comprised of all directors of radiologocal health programs in the fifty states, the territories and certain large municipal agencies. The Conference was formed approximately nine (9) years ago to serve as a mechanism for providing a more functional means of exchanging information between state and federal agencies, as well as between states themselves, in areas of mutual concern or interest.

The over-all goal of the Conference is to assure; that the patient who is to receive radiation, either diagnostically or therapeutically; the worker in radiation; the consumer; and the general public at-large receives the lowest amount of radiation exposure consistent with the benefit derived from such exposure.

In keeping with this goal and the policy of serving as a means of federal-state, state-to-state coordination when certain radiation problems warrant specific consideration, the Conference establishes task forces with respresentative membership from appropriate federal and state agencies. The purpose of the task forces are to evaluate, discuss and subsequently to develop resolutions to the identified problems. These task forces meet, as required, through the year to specifically address their assigned tasks, and then annually the total Conference meets to consider the task force recommendations of the proposed resolutions to the identified problem. The proceedings of these annual meetings are published.

Although I do not have sufficient copies for the entire Committee, I would like to submit to the Chairman, copies of these Proceedings for the last nine (9) annual meetings. These Proceedings will identify the issues considered at that time to be problems and the Conference's actions to address those problems.

The current radiation problems which we perceive that need resolution, in the order of their priority, as as follows:

I. The reduction of unnecessary radiation exposure from x-rays used in the healing arts profession. Unnecessary radiation exposure in this area can be caused by:

a. Inadequate training in radiation protection techniques and procedures, and in some cases inadequate training in the actual diagnostic and/or therapeutic procedures being performed. While this inadequate training applies primarily to the operators of the x-ray sources, in many cases to the non-radiologist practitioner supervising the operator is also in need of specific radiological training.

b. The non-efficacious use of x-ray sources by the prescribing practitioner. Studies have been published by the healing arts profession questioning certain x-ray exams or procedures as being unnecessary. Some examples of the exams or procedures questioned are: (1) exams for medical-legal protection of the practitioner, although not necessarily medically indicated; (2) routine pre-employment x-rays regardless of any pre-determined medical need; and (3) routine pre-emission of patients into hospitals.

c. Inadequate quality control programs within x-ray facilities to assure consistent, reproducible radiographs. This lack of quality control results in re-taking of the film, thereby essentially doubling the exposure to the patient.

d. Improperly designed x-ray systems.

II. The reduction of unnecessary radiation exposure from radioactive materials used in nuclear medicine. Unnecessary exposure in this area is caused by:

a. Some inadequately trained personnel, particularly those in the allied health profession.

b. Non-efficacious use of certain diagnostic radioactive elements vs. another radioactive element which provide basically the same diagnostic information, but with different amounts of radiation close to the patient and radiation worker.

III. The reduction of unnecessary radiation exposure to the general population from various environmental radiation sources. These include both ionizing and nonionizing radiation sources. Specifically, in the ionizing area:

a. Natural sources, such as, (1) natural radioactive materials in phosphates; and, (2) natural radioactivity in commercial and private caves, and (3) other sources of natural radioactivity.

b. Uranium fuel cycle sources, such as (1) mill tailings; (2) transportation accidents; and, (3) waste disposal.

Specifically, in the non-ionizing area:

a. Microwave sources, such as radar and microwave communication systems.

b. Possible radio frequency transmission sources, such as, television transmitting units.

IV. The reduction of unnecessary radiation exposure to the radiation worker from both ionizing and non-ionizing radiation sources.

In the ionizing area, specific interest in the unnecessary exposure from the use of radioactive materials and x-rays in industrial radiography, and the use of certain types of medical x-ray sources, such as fluoroscopes.

In the non-ionizing area, specific interest in the unnecessary exposure in the industrial use of microwave and laser systems.

V. The reduction of unnecessary radiation exposure to the consuming public from both ionizing and non-ionizing sources.

In the ionizing area, the products which are of concern are products which are not designed to emit radiation, but which do emit radiation incidental to their primary use. An example: the color television set. It appears that most products which do produce ionizing radiation incidental to their primary use are currently being manufactured to meet the standards of safety established by the Bureau of Radiological Health in FDA.

In the non-ionizing area, the microwave cooking oven is of most interest. Presently, the control of microwave exposure from these ovens are by emission rate standards from the specific sources, which is where such standards should be applied. However, it appears that there is a need for minimum acceptable exposure rates of people (general population) in addition to the source emission standards.

In addition to these problems relating specifically to radiation sources, the Conference would like to address other problem issues which affect state radiation control programs in their efforts to protect the citizens of their states from unnecessary radiation exposure.

I. Loss of State Training. There has been a significant loss of radiological training of state personnel from the Federal Government, with the exception of training provided to states by the Nuclear Regulatory Commission (NDC). The availability of training, either direct training by the Federal Government, or financial support of such training, in the areas of x-ray protection and radiation protection of the environment is not available, or if available, only to a very limited degree. In the 1960's such training was available, and many state radiation protection personnel received excellent training from various x-ray and environmental courses provided by the Federal Government. There are such courses available at some major teaching institutions, but the costs are rather substantial, especially when related to small training-related budgets at the state level. Additionally, the courses which were previously provided by the Federal Government were generally more oriented to the specific state governmental problems in controlling radiation than those courses available through the major teaching institutions. There is also one great advantage of such courses being provided by the Federal Government. Students, who are from various states, will learn techniques and procedures from the same source of training, and the application of these techniques and procedures should result in more uniformity than if the various state students obtained training at different institutions.

II. Overlapping Federal Jurisdiction in Radiation Protection Activities. It appears that there are both overlapping jurisdictions from Federal agencies to Federal agencies, and from Federal agencies to state agencies. To put these problems in perspective from a states viewpoint, listed below are the Federal agencies which we have identified which have some responsibility in the control of radiation:

(1) Food and Drug Administration: BRH: X-ray, Non-ionizing, manufacturing regulations and field compliance. Bureau of Drugs: Radiopharmaceuticals—manufacture. Bureau of Foods: Radiation in/on foods.

(2) Nuclear Regulatory Commission: Regulations for the use of radioactive materials known as By-product, Source, and Specific Nuclear Materials. (It should be noted that these types of materials exclude naturally occurring and machine artificially produced radioactive materials.)

(3) ERDA: Large in-house activity, internal regulations and inspection, "Emergency Assistance for radiation accidents," IRAP.

(4) National Bureau of Standards: Calibration of sources and instruments.

(5) Department of Agriculture: Radiation levels in cheese, butter, milk.

(6) Environmental Protection Agency: Establishing guidelines in radiation protection and monitoring of the environment for radioactive contamination.

(7) U.S. Department of Transportation: Extensive regulations on hazardous materials for vehicular transportation. Also under D.O.T. are:

a. Federal Aviation Administration: Part of D.O.T. covering air transport of radioactive materials. Extensive regulations (F.A.R. Pt. 103).

b. U.S. Coast Guard: Regulations on water transport of radioactive materials.

(8) Department of Defense: In-house responsibility for regulatory affairs; participates with states in emergency response if military radiation sources are involved in an accident.

(9) GSA: Emergency response planning.

(10) OSHA: Regulations on occupational exposures criteria. Strong compliance program.

(11) Federal Bureau of Investigation: Has responsibility for nuclear extortion threats assisted by local, state and other Federal agenices.

(12) U.S. Postal Department: Regulations on shipping radioactive material by mail.

Although the Conference has most contact with the FDA, NRC, and EPA, state programs in radiation protection will, at one time or another, work with or have contact with, one of the agencies listed above. Many of these agencies are charged by legislation to develop regulations, and the legislation or the regulations promulgated under the legislation put pre-emptive type clauses related to state regulation in the same area.

Although for national uniformity, these type pre-emptive clauses are understandable, they can create problems at the state level in proper compliance of all such pre-emptive clauses simultaneously. For example, as related to radiation protection, the following pre-emptive clauses appear in Federal legislation or Federal regulations:

(1) "Compatible with": Atomic Energy Act of 1954, as amended. Specifically, Section 274 of the Act.

(2) "Identical too": PL 90–602

(3) "As effective as": OSHA Act

In light of the many federal agencies having responsibility in radiation protection, there are areas of duplication, and in many cases, what appears from the states viewpoint, confusion at the federal level on matters relating to radiation protection. In recognition of this problem, the Conference adopted a Resolution in 1973, urging the Congress to take necessary legislative action to consolidate the various Federal responsibilities. A copy of this resolution is included with the attachment of resolutions discussed under answer two.

The Conference currently supports the concepts of the Resolution, although we now realize that one agency may not be feasible. The Conference does strongly support the need for consolidation of the many and varied activities in radiation protection at the federal level. If consolidation is not a viable option, the developments of interagency agreements which clearly identify the responsibilities of the various agencies may help.

As an example of how various agencies present a confused position to states, in the development of X-ray standards. It appears that both the FDA and EPA are developing standards which relate to the use of medical X-ray.

III. Loss of Direct Financial Support to Radiation Programs at the Federal Level. In the 1960's, funding to states from the federal government was available through formula grants, specifically identified for radiation protection activities. However, these funds for radiation protection activities were stopped in 1968, and since then the state radiation control programs have had to compete with other state programs for funds available through comprehensive health planning grants, and funds provided states through the federal revenue sharing program. This strong state program competition for available funds has resulted in a slow growth of available monies in radiological protection activities in some states.

Another problem which has impacted on the state radiation protection budgets is the necessity of setting artificial priorities in the expenditure of funds due to certain federal requirements. An example is the need to develop state emergency response plans for fixed nuclear facilities, such as nuclear power reactors. These type facilities are entirely regulated, from a radiological health and safety viewpoint, by the Nuclear Regulatory Commission. However, for such a facility to be licensed by the NRC, the operator must demonstrate proper planning for emergencies through coordination with state and local agencies. The Conference fully recognizes the need for this coordinated planning, but the development of such plans, which require many man-hours, may not be in line with estabilshed priorities of state budget expenditures for more crucial public health issues such as protection in the use of X-rays.

In addition to the need of emergency planning, these fixed facilities also result in the need for environmental monitoring at the state level. Again, the Conference believes that monitoring of such facilities should properly be the responsibility of the states but the cost for such monitoring has effected the expenditure of monies from the total state radiation protection budget.

IV. Lack of Uniform National Criteria: There is an urgent need for national criteria areas of radiation protection. Such criteria is not only needed for proper protection of the public, and worker, but needed for the uniform application of regulations throughout the country. Specifically, there is a need for national guidance and criteria in the following areas:

a. The regulation and use of radioactive materials not presently covered under the Atomic Energy Act. Specifically, radioactive materials which occur in nature or are produced artificially by machines. This is an area of radiation control which has a significant gap. The Atomic Energy Act provides for regulatory control of by-product, source and Special Nuclear Material by the Nuclear Regulatory Commission, or an "Agreement State." However, in most states which do not have an agreement under the Act, there is varied control of naturally occuring or artificially produced radioactive material. "Agreement states" in general provide the same type regulation for both types of radioactive materials. There are five non-agreement states; Illinois, New Jersey, Pennsylvania, Michigan and Virginia, which also provide licensing requirements for the use of naturally occurring and artificially produced materials. There may be the need for federal legislative action in this area so that there is uniform effective control for naturally occurring and artificially produced radioactive materials.

b. Uniform national criteria is strongly needed relative to the siting, regulation, and perpetual care of "low level" radioactive waste disposal facilities. There are six commercial sites now dedicated for the disposal of radioactive waste. However, there are no established national criteria or guidance for, "what is" and "what is not" acceptable siting, regulation, and perpetual care fee collection for the operation of such sites. It is my understanding that the NRC and EPA are working toward the development of such criteria and guidance, but that such guidance may still be several years away.

Question 2. Please discuss the resolutions which the Conference has developed within the last 7 years with respect to radiation health and safety. Please include a status report on these resolutions, the current additional recommendations on radiation health and safety which should be addressed either by Congress or the federal executive agencies.

Answer. The Conference has adopted 14 Resolutions since its establishment in 1968. Copies of these resolutions are shown on attachment I. Appended to these Resolutions is a summary of each Resolution.

The first Resolution of the 1971 Conference, and the Resolution of the 1974 Conference relate to the credentialing of persons administring diagnostic x-rays. The majority of the Conference membership continues to support the position that there is a need for programs to assure that only adequately trained and experienced persons administer diagnostic x-rays to patients, and that the most effective method to assure this training and experience is through a credentialing mechanism. It should be noted that this position represents a majority of the Conference, but there are specific states which do not concur with credentialing as a mechanism for assuring the adequacy of training, and have adopted policies relative to that position. In respect to the implementation of a credentialing program, a majority of the members of the Conference believe that implementation of credentialing will be most effective at the State level, but strongly support the development of guidelines and recommendations at the Federal level, so that there will be a uniform application of credentialing throughout the United States.

Currently, there are 9 states and Puerto Rico which have enabling legislation and 3 states which have Attorney General opinions indicating authority for legislation for the credentialing of persons administering diagnostic x-rays. Of the states which have enabling legislation 5 states and Puerto Rico either have ongoing licensing programs or will have licensing programs in the near future.

In respect to the 2nd Resolution at our 1971 Annual Meeting, the Conference continues to support the position as expressed in this Resolution. There are presently 30 states which license the use of Radium, and several states regulate Radium through a registration program, but with limited enforcement action.

The Conference continues to support the concerns as expressed in Resolution No. 3 of our 1971 Annual Meeting. Several states have provided training programs and curricula for dental assistants, and many state dental associations or boards have adopted requirements of training and radition safety for dental assistants.

In respect to Resolution No. 4 of our 1971 Annual Meeting, the Bureau of Radiological Health, FDA, has responded to our Resolution by the development of several different type training packages available both to the users of radiation and to state programs. The Bureau is to be complimented for their efforts in this area.

Although the Conference endorsed Resolution No. 5 of our 1971 Annual Meeting, the recommendations of this Resolution have not been adopted into the suggested state regulations. However, it is my understanding that a majority of states have independently included the recommendations of this Resolution to administrative procedures.

The Bureau of Radiological Health, FDA, does provide financial assistance to states, under contract, which desire to assist the Bureau in the inspection of newly manufactured diagnostic X-ray equipment and components manufactured under the Federal Performance Standard. Therefore, the Conference feels that the recommendations of this Resolution have been answered.

In respect to the recommendations as indicated in the 2nd Resolution of our 1972 Annual Meeting, we believe that efforts are being made to develop performance criteria and survey methodologies for photofluoroscopic machines through task forces working toward amendments to the suggested state regulations.

The position of the Conference relative to the Resolution of our 1973 Annual Meeting was addressed in Question 1.

The Resolution of our 1974 Annual Meeting was addressed under Answer No. 1 of this section.

Recommendations as expressed in the 1975 Resolution of the Conference is still supported by the members of the Conference. In respect to the current status of this Resolution, the problem of uranium mill tailings piles continues to be a problem and to my knowledge there has been no Federal financial support for any remedial measures in correcting the potential hazards from these mill tailings piles.

We believe the Nuclear Regulatory Commission has properly responded to our request as expressed in Resolution No. 1 of our 1976 Annual Meeting.

Likewise, we believe that the recommendations as expressed in Resolution No. 2 of our 1976 Conference have been properly addressed, since the technical assistance activities of the Environmental Protection Agency as expressed in this Resolution have been restored, and the states are currently being provided with the needed technical assistance.

We believe that the expressions of Resolution No. 1 under our August 1976 actions, will be properly addressed through task forces which have been formed to address the quality assurance issue, not only in the area of nuclear medicine, but in diagnostic x-ray and eventually therapeutic x-ray.

The Conference feels that our Resolution No. 2 of our August 1976 actions have been properly addressed by the Nuclear Regulatory Commission.

Question 3. Please set forth your reasons for the resolutions calling for clarification or centralization of federal radiation safety and health responsibilities and activities. Discuss problems of state and federal coordination with respect to transportation, licensing, inspection of radiation devices, etc.

Answer. The major reasons calling for clarification or centralization of radiation activities at the federal level were addressed in question No. 1. However, some further discussion of the specific problems of state and federal coordination is warranted. The transportation of radioactive material is generally regulated by the Department of Transportation, although certain special types of shipments of radioactive material come under regulations of the Nuclear Regulatory Commission. Although the regulations which have been adopted by the Department of Transportation and the Nuclear Regulatory Commission for the packaging and shipment of radioactive materials appears to be adequate, the major problem seems to be one of inspecting for compliance to these regulations. The Department of Transportation seems to have only a limited number of field staff, expertise in radiological health matters, to perform inspections of the radioactive material in transit. Many states conduct their own inspections of radioactive materials being transported throughout their states, and some currently have agreements with the U.S. Department of Transportation for a coordinated effort in the enforcement of safety standards. Although previously discussed under answer No. 1, as relates to state/federal coordination, it cannot be overemphasized that there appears to be a gap in the control of radioactive materials not falling within the jurisdiction of the Atomic Energy Act. Specifically, the control of naturally occurring and machine artificially produced radioactive materials needs immediate attention, and possible federal legislation, to assure that there is uniform control for the protection of the public health and safety.

In respect to the inspection of radiation devices, the state programs have the responsibility for the inspection of the use of the radiation producing machines while the responsibility for the inspection of radiation producing machines at the manufacturing point is within the Food and Drug Administration. The Conference strongly supports the position that the states should maintain the responsibility for the inspection of the use of radiation producing machines. The majority of the members of the Conference also support the need for the inspection of devices manufactured under the Federal X-ray Performance Standard, and several states have entered into a contract with FDA to perform these compliance inspections. Some states have indicated difficulty in participating under this contract, mainly due to the potential problem of establishing a program with federal financial assistance under the contract, with the potential at a later date of the funds not being available and, therefore, resulting in the hiring of personnel under the conditions of a short time basis. I believe that more states would be willing to sign contracts with the FDA to perform x-ray inspections for compliance of the x-ray performance standard, if there could be assured continuity from one year to the next of financial assistance from the FDA.

Question 4. Please provide the Committee with a background and history of the Conference and discussion of any relationships established with the Federal Government, and any programs undertaken by the Conference which deserve mention.

Answer. The Conference of Radiation Control Program Directors, Inc. is an organization comprised of directors of radiation control programs in all states, territories, District of Columbia and several large local control agencies. The Conference was established approximately nine (9) years ago as a mechanism of information exchange between state and Federal officials. Since formation, the Conference has shown a continued growth in terms of membership, expertise and areas of scientific/regulation concern. While initial interests of the Conference were concentrated in areas of x-ray machine operation, occupational radiation exposure and regulatory control of radioactive material users, the scope of conference interests has greatly expanded into facets of population radiation exposure which were not as evident as when the Conference began.

Since the Conference was built upon the need for public health and safety from hazards of radiation, expanded use, technology and complexity of radiation sources has created an increased potential for public harm. Because the Conference is simply a reflection of the concerns of its members, we are providing to the Chairman, copies of a "Report of State and Local Radiological Health Programs, Fiscal Year 1975." This report is published by HEW and summarizes the status of state programs.

In this report, the HEW reported a total state and local expenditure of nearly 12 million dollars. This level of spending also represented an increase of 15 percent over fiscal year 1974 levels. The Conference points out these figures as an indication of the degree of state and local concern to provide public protection in a time of shrinking state and local resources. To what extent local or state resources will continue to be provided is, however, a matter of serious concern.

The Conference began and continues to grow with support from Federal agencies. In fact, most state radiation programs actually started as a result of model legislation, grants and technical assistance provided by the Bureau of Radiological Health, HEW. Since that time, the involvement of Federal authorities and agencies has grown significantly as stated earlier in question one. Yet, Federal support in terms of training and grants has dropped dramatically.

The Conference itself is supported primarily by three Federal agencies; FDA/BRH, EPA and NRC. Through the Conference, individual states are offered direct opportunities to discuss and oftentimes, develop programs of shared interest and/or responsibility. The Conference provides to the Federal agencies, a mechanism of direct interchange of ideas, views and concepts on which Federal activities are often developed. Interest shown in the Conference by other Federal agencies tends to indicate the success that their unique state-Federal relationship is viewed by other agencies.

Since the primary Federal agencies have differing areas of jurisdiction responsibility or interest, the Conference's relationship with a particular agency is based upon the appropriate area of interest. While obviously, the Conference/Federal agency interest is cemented by common concern for radiation protection, for the American citizen, the level of individual agency involvement with the Conference is based upon the Federal jurisdiction and how it relates to state government. For example, the Bureau of Radiological Health concentrates with the Conference in areas of x-ray protection, the Nuclear Regulatory Commission in areas of radioactive materials regulation, and the Environmental Protection Agency (Office of Radiation Programs) in areas of environmental radiation and standards guidance. The Conference also works with the National Bureau of Standards on items of equipment standardization and measurement, the Department of Transportation in areas of radioactive materials transport and the Department of Labor in occupational regulation. The Conference also has maintained contact with the Energy Research and Development Administration (ERDA) in matters relating to radioactive waste management.

When matters and/or issues arise concerning a new or changing radiation problem, the identifying agency or state will bring up this problem to the Conference. If the problem is of an "information only" nature, a distribution of this information occurs within the appropriate channel. If the problem is one in which a short term solution is required, direct coordination between appropriate jurisdictions is attempted by the Conference. If, however, the problem is one in which trends must be identified, impacts measured and action program developed, the Conference will address it in a task force approach. The problem of increased natural radiation levels resulting from the mining and refinement of materials such as phosphate can be used as an example. At the Conference's 1974 held meeting, a workshop was held to look into the problem caused by high radiation levels from the phosphate industry. The state of Florida had identified this as a potential problem. Based upon the workshop's suggestion, the Conference formally appointed a task force to scope the problem and to identify needs for action. Five state representatives of the Conference, who were from states potentially having this problem, were assigned as members. In addition, appropriate Federal agency representation was included.

The task force held meetings at which they visited sites where this problem was acute and research methods of improving and/or suggesting plans of action for the states. In June, 1977, this task force issued a draft report. The report of this task force, as well as a report of a task force on Perpetual Care and Bonding will be transmitted to the Committee Chairman.

Over the years, numerous problems have been addressed by this Federal/state task force mechanism. During this past year alone, the following areas were considered; x-ray quality assurance, soil contamination limits, emergency response planning, personnel dosimetry, notification of radioactive shipments, public impact of nuclear medicine practice, credentialing, mammography, radioactive waste management and others.

CONFERENCE OF RADIATION CONTROL DIRECTORS

RESOLUTIONS SUMMARY

Third Annual Conference—1971

Resolution No. 1—A recognition by the Conference of the necessity for the credentialing of both x-ray operators and supervisors of operators, with recommendations of criteria for us in credentialing.

Resolution No. 2—A recognition of the specific hazards in handling Radium and Radon, with recommendations for states to undertake a Radium licensing program.

Resolution No. 3—A recognition for the need of training in radiation protection for dental assistants, with recommendations for state dental agencies to adopt rules and regulations requiring training and testing in radiation safety, and for state radiation protection programs to develop recommended training courses for such personnel.

Resolution No. 4—Recognition for the need of continuing education for all radiation users, with recommendations that the Bureau of Radiological Health (BRH, FDA) develop training courses to address the need.

Resolution No. 5—Resolution of five southern states, endorsed by the Conference, regarding the proper wearing of personnel monitoring devices during fluoroscopic procedures.

Fourth Annual Conference—1972

Resolution No. 1—Recognition of the need for Federal financial support to states which assist BRH in the inspection of x-ray equipment falling under the requirements of PL 90–602.

Resolution No. 2—Recommendation to HEW for clarification of an issued policy statement entitled "The Chest X-Ray as a Screening Procedure for Cardiopulmonary Disease," with a further recommendation that HEW, in cooperation with the Conference, develop performance criteria and survey methodologies for photofluoroscopic machines.

Fifth Annual Conference—1973

Resolution—Recognition of the need for consolidation of radiation protection activities at the Federal level, with recommendations to the Congress to take necessary legislative action for such consolidation.

Sixth Annual Conference—1974

Resolution—A second resolution of the Conference (1st being Resolution No. 1 at the 1971 Annual Meeting) recognizing the need for assuring the proper training and experience of persons administering diagnostic X-rays, with recommendations to Congress and State Legislatures for the adoption of legislation addressing this need.

Seventh Annual Conference—1975

Resolution—Recognition of the potential hazard of uranium mill tailings piles, with recommendations that the cost for remedial measures on the piles created prior to the implementation of the National Environmental Policy Act be supported financially by Federal funds.

Eighth Annual Conference—1976

Resolution No. 1—Recommendation to NRC to review and purge its regulations which are not in step with current radiation protection policy.

Resolution No. 2—Recognition of the loss of technical assistance to states from the Environmental Protection Agency, with a recommendation that the President and Congress make efforts to restore this loss of assistance to the states.

August 1976

Resolution No. 1—Recognition of the need for a quality control program in nuclear medicine scintigraphic instrumentation, with recommendations of performance parameters for such a quality control program.

Resolution No. 2—Recognition of the potential loss of records of disposal for radioactive materials, when such disposal occurs in many locations, with a recommendation to the Nuclear Regulatory Commission to amend their regulations on blanket authorization for certain types of soil disposal to be modeled after their incineration regulations.

RESOLUTIONS

THIRD ANNUAL CONFERENCE 1971

Resolution 1

Whereas X-rays and radioactive materials were discovered in the last century and both have been used for diagnostic and therapeutic purposes since their discovery;

Whereas possible hazards to patients and the general public from both of these radiation sources have been studied and the data published, the unnecessary exposures from X-rays generally are greater than the exposure from radioactive materials; and the unnecessary exposures from radioisotopes are currently controlled much more adequately than control of X-ray exposures;

Whereas the effort expended for control of exposure from X-rays has been less than the effort to control the proper use of radioactive materials;

Whereas the genetically significant dose from X-rays is increasing rapidly as is the total use of X-rays on humans;

Whereas curtailment of the genetically significant dose from exposure to unnecessary X-rays is relatively easy;

Whereas radiation can be considered an agent which pollutes or disturbs the human environment and the admistrator of E.P.A. stated, and it was published in the proceedings of the State and Territorials Health Officers Conference December 7–10, 1970, that "the Federal Government is one of the worst polluters in the whole country . . . will take the lead in cleaning its own house";

Whereas "the States are the primary enforcement arm in environmental control"; and

Whereas the control used prior to 1963 was on the equipment and not the user: Therefore be it

Resolved, That the Conference of Radiation Control Program Directors recognize the necessity for people control in the use of X-rays on humans and that this control be manifested or implemented by adopting some general regulations, guidelines, and above all qualification for all users of X-rays for medical and dental diagnostic and therapeutic purposes; and be it

Resolved further, That the radiation protection component of all user qualifications be the same for all category of users and that the attached document for technologists entitled "Minimum Hours Required for Approved Training Programs in the Indicated Categories", plus "Licentiates Training Hours for Limited Permit Operators" and "Licentiate Minimum Didactic Training Hours for Limited Permit Operators" plus the ASRT and ACR requirements for the registered X-ray user be accepted as guidelines for all X-ray users or supervisors of users; and be it

Resolved further, That X-ray users employed by the Federal Government not be exempted from these user qualifications; and be it

STATE OF CALIFORNIA, DEPARTMENT OF PUBLIC HEALTH, BUREAU OF RADIOLOGICAL HEALTH

[Minimum hours required for approved training programs in the indicated categories]

Category	Radiologic technologists															
	Number of subjects	Radiation protection	Anatomy and physiology	Radiological physics	X-ray technical factors	Equipment operation and maintenance	Film processing	Medical terminology	Medical ethics	Nursing procedures or patient care	Positioning	Film critique	Total classroom	Total clinical experience	Total program (hours)	Total program (months)
Photofluorographic chest	5	27	3	0	3	5	0	0	0	0	2	0	4-0	0	4-0	[1] ¼
Chest	11	54	10	27	10	10	10	10	2	4	5	10	152	368	520	3
Leg	11	54	10	27	10	10	10	10	2	4	5	10	152	368	520	3
GI	11	54	27	27	10	10	10	10	2	8	27	20	205	835	1,040	6
GU	11	54	27	27	10	10	10	10	2	8	5	20	183	857	1,040	6
Skull	11	54	27	27	10	10	10	10	2	4	27	20	201	839	1,040	6
Musculosketal	11	54	54	27	10	10	10	10	2	8	54	40	279	1,721	2,000	12
Dental laboratory	10	54	20	20	10	10	10	5	2	0	25	30	186	1,314	1,500	9
Chest and extremities	11	54	27	27	10	10	10	10	2	8	27	25	210	470	680	4

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[1] Difference.

LICENTIATES OF THE HEALING ARTS

RECOMMENDED MINIMUM TRAINING HOURS FOR LIMITED PERMIT OPERATORS

Permit category	Minimum training hours		
	Didactic	Clinical	Total
Musculoskeletal system (excluding skull, including spine)	80	160	240
Skull (without contrast media)	66	80	146
Chest	62	40	102
Gastrointestinal (with contrast media)	84	160	244
Genitourinary (with contrast media)	68	80	148
Photofluorographic	62	40	102
Leg: knee and distal portion	62	40	102

RECOMMENDED MINIMUM DIDACTIC TRAINING HOURS FOR LIMITED PERMIT OPERATORS

Subiect	Permit category—Recommended minimum didactic training hours						
	Musculo	Skull	Chest	GI	GU	PF	Leg
Anatomy and physiology	6	4	4	8	6	4	4
Positioning	16	8	4	16	8	4	4
Radiographic technique	8	4	4	8	4	4	4
Film processing	8	8	8	8	8	8	8
Equipment operation and maintenance	2	2	2	4	2	2	2
Radiological physics and radiation protection	40	40	40	40	40	40	40
Total hours	80	66	62	84	68	62	62

Note: These recommendations have been prepared for the California State Bureau of Radiological Health by: Reynold F. Brown, M.D. and Bruce M. Burnett, M.S. Radiological Health Sciences Education Proiect Department of Radiology, University of California, San Francisco.

Resolved further, That user qualifications include standards of education, training, and experience for each category of X-ray user and the prescribed means for assuring that the established qualifications and standards are met, whether it be by certification, licensing or other recognized people control.

Resolution 2

Whereas, the training and qualifications of physicians, nurses, hospital aides and technicians in the safe handling of radium and radon is reflected in the number of radiation incidents and/or unnecessary exposures: Therefore be it now

Resolved, That all states undertake a radium licensing and regulatory radiation protection program which will assure the adequacy of hospital staff training in the safe utilization of radium and radon. Hospital staff that become involved with radium or radon treatments shall be knowledgeable in fundamentals of radiation safety, safe handling procedures, accountability, emergency procedures and physical radiation characteristics of radium and radon.

Resolution 3

Whereas, it is recognized that health delivery systems are in a crisis and that increasing demands for health services call for solutions which will make quality health services more readily accessible to the patient at a reasonable cost;

Whereas it is recognized that one solution in the provision of quality dental care is to assign expanded duties to dental auxiliaries such as dental assistants, thereby allowing the dentist to apply his time and skills to the provisions of those services where his professional training and judgment are most needed;

Whereas it is recognized that in certain states, the state dental practice act has been amended to authorize expanded duties for dental auxiliaries; and

Whereas it is recognized that dental assistants can be trained in the principles of radiation safety sufficient to enable them to make radiographic exposures of patients, in a safe and proper manner while under the direct supervision of the dentist: Now, therefore, be it

Resolved, That the Conference of Radiation Control Program Directors urge that State dental agencies, when so authorized by statute, adopt rules and regulations pertaining to the expanded duty for dental assistants of making radiographic exposures of patients, under the supervision of the dentist and after satisfactory completion of a radiation safety training course; and, be it

Resolved further, That the Conference urge that State regulatory agencies develop and implement an adequate program of radiation safety training courses which will be available to all dental assistants who will be authorized by rule or regultion to perform radiographic exposures upon patients under the supervision of a dentist.

Resolution 4

Whereas medical X-rays are the major sources of public exposure to man-made radiation; and

Whereas the medical diagnostic use of radiopharmaceuticals is rapidly increasing; and

Whereas the increasing use of all radiation sources is resulting in increased occupational and public radiation exposure; and

Whereas the Conference believes that continuing education and training is essential for all users in order to eliminate unnecessary radiation exposure; and

Whereas there is a great need for adequate continuing education and training for all users: Therefore, be it

Resolved, That the State radiation control programs should:

strongly encourage users of radiation sources to seek continued training in proper techniques and radiation protection,

actively promote and assist in the development of such training in hospitals, other educational institutions and societies, and

exchange information on such activities for the mutual benefit of all programs; and, be it further

Resolved, That the Bureau of Radiological Health should develop effective training material and courses of instruction for users, provide such material to the State programs, and actively assist the State program in their user training activities.

Resolution 5

The Southern States of Alabama, Florida, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee, hereby resolve:

(1) that consistent guidance be provided to fluoroscopists and bedside radiographers regarding the location of personnel monitoring devices worn during fluoroscopy and bedside radiography;

(2) that if only one personnel monitoring device is worn during fluoroscopy and bedside radiography, it should be worn outside the protective apron at the neck-line position;

(3) that the location where the personnel monitoring device is worn should be recorded as an integral part of a fluoroscopist's and bedside radiographer's personnel monitoring record;

(4) that the Conference of Radiation Control Program Directors should endorse this resolution and investigate the practicability of amending the Council of State Government's suggested State Regulation for control of radiation to provide for Item No. (3) above.

FOURTH ANNUAL CONFERENCE 1972

Resolution 1

Whereas the implementation and enforcement of the Federal performance standards for diagnostic x-ray equipment will require the active participation of State and local radiological health personnel in the inspection and surveys of new x-ray equipment covered by these standards according to Federal evaluation procedures;

Whereas such additional workload on existing State radiological health programs will require additional funding resources not available within the States; and

Whereas Public Law 90–602 in Section 360E authorized the Secretary of the Department of Health, Education, and Welfare to reimburse the State and local jurisdictions for enforcement services required by the Act: Be it

Resolved, That the National Conference on Radiation Control make it a matter of record, its concern that the State and local radiation control programs will not be able to embark on the additional inspection requirements imposed by the Federal standard without assurance that such necessarily expanded programs will be reimbursed on a basis to be negotiated with such individual jurisdictions.

Resolution 2

Whereas the Department of Health, Education, and Welfare issued on April 24, 1972 a policy statement entitled, "The Chest X-Ray as a Screening Procedure for Cardiopulmonary Disease" endorsed by the American College of Radiology, the American College of Chest Physicians, and the National Tuberculosis and Respiratory Disease Association; and

Whereas the Conference of Radiation Control Program Directors has reviewed this statement and attendant press releases and finds significant confusion in the interpretation of the following items:

1. The intended audience (medical community, public health agencies, x-ray machine users, or the general public);
2. The x-ray equipment included (photofluorographic, mobile portable, and conventional fixed radiographic);
3. The type of facilities included (mobile vans and stationary facilities such as clinics); and

Whereas State radiation control programs are directly affected by the interpretation of this policy statement: Be it hereby

Resolved, That the Department of Health, Education, and Welfare clarify this policy statement in the areas outlined above; and, be it further

Resolved, That the Department of Health, Education, and Welfare, in cooperation with the Conference of Radiation Control Program Directors, review the need to develop performance criteria and survey methodologies for photofluoroscopic machines.

FIFTH ANNUAL CONFERENCE 1973

Resolution

Whereas the responsibility for the protection of the public and worker from exposure to radiation has been significantly fragmented at the Federal level;

Whereas this fragmentation of responsibility is divided among the Atomic Energy Commission, the Food and Drug Administration, the Environmental Protection Agency, the Department of Transportation, the Department of Labor, the Office of Emergency Preparedness;

Whereas this fragmentation is further exhibited between regional offices and headquarters offices with certain of these Federal agencies;

Whereas this fragmentation results in duplication, inefficiency, contradictions, and complexities in communication: Therefore, be it

Resolved that the Conference of Radiation Control Program Directors, urge the Congress of the United States to consider this serious problem of fragmentation and take the necessary legislative action to consolidate the various Federal responsibilities relating to radiation protection of the public and worker within one agency.

SIXTH ANNUAL CONFERENCE 1974

Resolution

Whereas there is a recognized need for assuring that persons administering diagnostic x-ray be adequately trained and experienced to assure safe and efficacious use of x-ray equipment for the protection of the public health and maximum benefits to patients;

Whereas the licensure programs operating in the States of California, New Jersey, New York and Puerto Rico provide a means of assuring the adequacy of training and experience of those persons operating medical x-ray equipment; and

Whereas legislation for implementing or continuing such licensure programs is now under consideration in both the U.S. Congress and State legislatures of some 10 States: Therefore, be it

Revolved The Conference urges the U.S. Food and Drug Administration to that the Congress and the several State legislatures adopt such legislation as is presently before them to assure the continuation or implementation of programs for licensure of operators of medical diagnostic x-ray equipment; be it further

Resolved The Conference urges the U.S. Food and Drug Administration to adopt a public policy supporting such legislation and that the Food and Drug Administration actively assist States in drafting State legislation and organizing an effective implementation of present and future operator licensing legislation.

SEVENTH ANNUAL CONFERENCE 1975

Resolution

Whereas, Uranium mill tailings piles are a real or potential hazard to the public;

Whereas, the uranium tailings piles are the results of mining for uranium fuel;

Whereas, uranium is necessary for energy production and national security;

Whereas, the benefits of economical electric power from nuclear power facilities is accessible to all U.S. citizens; and

Whereas, the cost of elimination of the health hazard of uranium mining tailing is prohibitive in cost to those States where they exist: Therefore, be it

Resolved, that the Conference of Radiation Control Program Directors recommends that any remedial measures on piles created prior to the implementation of the National Environmental Policy Act be accomplished at total Federal expense, and that when any such remedial measures are taken, it should be with the approval of State and local government.

EIGHTH ANNUAL CONFERENCE 1976

Resolution 1

Whereas regulations are constantly under revision;

Whereas there is a tendency to perpetually add to regulations;

Whereas seldom is any authorization which no longer having beneficial use removed from regulations;

Whereas regulations must be continually justified to those being regulated and the general public; and

Whereas a specific license can be used for those exceptional situations where the use is justified on a case-by-case basis: Therefore, be it

Resolved that the Conference petition the NRC to review its current regulations and purge those portions of the regulations not in step with present day radiation protection philosophy.

Two examples of the need for review are the general license of source material to physicians and pharmacists, and the Exemption from Licensing of scandium-46 for well logging.

Resolution 2

Whereas the technical assistance activities of the Environmental Protection Agency, including analytical laboratory support and radiation monitoring has been of immeasurable help to radiation control programs of the States, thereby benefitting the public health of the nation; and

Whereas the Environmental Protection Agency has been directed to reduce or eliminate the provision of such a system to the States: Be it, therefore,

Resolved, That the President and Congress of the United States be made aware of the concern of the Directors of State radiation control programs in the loss of such technical assistance and that the President and Congress be encouraged to make every effort to restore and perhaps increase this important and necessary function of the Environmental Protection Agency as one means to insure the continued protection of the Nation's public health and safety through cooperative State/Federal radiation control programs.

AUGUST 1976

Resolution 1

Whereas the continuous improvement of nuclear medicine scintigraphic instrumentation will yield high quality diagnostic images;

Whereas such images are essential to the evaluation and clinical management of nuclear medicine patients;

Whereas it should be the goal of all nuclear medicine departments to maintain a high level of diagnostic accuracy in interpreting scintigraphic images; and

Whereas such accuracy can be achieved in part by insuring the standardization of the performance of scintigraphic imaging instrumentation: Be it

Resolved, That scintigraphic instrumentation used to collect nuclear imaging data shall be quality control tested each day of use for minimization of variability in the following performance parameters:

a. Uniformity—the ability to produce a uniform image of a uniform "flood" source.

b. Spatial distortion—the ability to image arrays of linear sources of radioactivity with a minimum of distortion.

c. Resolving power—the ability to produce and display images of an array of radioactive sources which shall be discernible as separate entities.

Resolution 2

Whereas disposal records, while invaluable for compliance inspections, leave a question of accuracy;

Whereas once material has been disposed of, there is a tendency to forget completely about its location and amount;

Whereas disposal records are not required to be kept indefinitely;

Whereas constantly land is being placed into other uses;

Whereas many states have adopted the model solid waste disposal act which prohibits certain disposals by burial;

Whereas state radiation regulations should not be in opposition to other regulations;

Whereas regulations should not promote action unbeneficial to man and his environment; and,

Whereas should an exemption be deemed desirable, specific license conditions can authorize such disposal by burial as appropriate to the situation: Be it

Resolved, That the Conference petition the NRC that the blanket authorization for disposal by burial in the soil found in 20 304 of 10 CFR Part 20 be amended in its entirety. It is recommended that amendment be modeled after the disposal by incineration statement in 20.305 of 10 CFR Part 20.

[The following information was subsequently received for the record.]

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

WARREN G. MAGNUSON,
Chairman, Committee on Science, Commerce and Transportation, U.S. Senate, Russell Senate Office Building, Washington, D.C.

DEAR SENATOR MAGNUSON: Thank you for the opportunity to further clarify some of the statements made during my testimony of June 29, 1977, on behalf of the Conference of Radiation Control Program Directors. I also appreciate the extension of my response time to your letter of August 15, so that I could accumulate more information from the various states. After receiving your letter a questionnaire was sent to all state radiation control directors addressing the specific questions raised in your letter. In addition to this questionnaire to the various states, I have also discussed some of the issues raised with some of the Federal agencies involved. I hope that the following answers to your questions accurately reflect the general consensus of those states that respond to my questionnaire, and information which I was able to obtain from the various Federal agencies with whom I had contact.

I will answer your questions in the order that they were asked in your letter.

Question 1. Please describe in more detail for the Committee what you mean by "regulatory programs"?

Answer. A state regulatory program, as related to radiation control, can be described as a program administered by a state agency to protect the citizens of that state from unnecessary radiation exposure by the enforcement of regulations pertaining to the safe use of radiation sources. Prior to the adoption of such regulations, most states, if not all, must first obtain authority to develop and adopt such regulations from the state legislature. This authority is usually granted through some type of enabling legislation, although in some instances the legislation may be specific as to the type regulations which are to be adopted, and in some cases the legislation may contain specific requirements regarding health and safety. In most cases, either the legislation and/or the regulations promulgated under the legislation carries significant penalties for violation of the laws or the regulations, which range from fines up to $5000 or imprisonment not to exceed six months or both fined and imprisoned. To enforce the regulations the state programs conduct routine inspections for compliance. When violations are discovered during these inspections, depending upon the severity of the violation, regulatory actions are taken which range from a notice of violation with request to comply, up through the issuances of orders, suspensions, revocations of licenses, and the imposition of appropriate fines. Usually the regulations provide for confiscation of sources if there is an immediate danger to the health and safety of its citizens.

Question 2. What do most State regulations entail?

Answer. Most state radiation regulations follow the Suggested State Regulations which have been developed by the Conference of Radiation Control Programs Directors, the U.S. Nuclear Regulatory Commission, and the U.S. Food and Drug Administration. These regulations generally conform to the recommendations made by the National Council on Radiation Protection and Measurements (NCRP). For states which have signed an agreement with the NRC, these regulations must be compatible with those regulations adopted by the Commission.

Question 3. How effectively are the regulations enforced?

Answer. The answer to this question is difficult, since to measure effectiveness demands a criteria or measuring stick as to what is effective and what is not effective. Many means could be used to measure effectiveness. In the case of a regulatory program, which enforces regulations, it appears that one of the better measuring sticks is the frequency of compliance and non-compliance by the radiation user. Therefore, using compliance as a way to measure effectiveness, most every state which responded, has indicated that there has been a substantial increase in the number of radiation users that are currently found in compliance compared with the percent of users that were found in compliance at the beginnings of their enforcement programs. As an example, one states experience showed that from the compliance records of 1965 through 1972, only 50 percent of dental facilities were in compliance with the adopted regulations. The record for 1977 indicates that 95 percent of dental facilities inspected were found in compliance with the regulations.

In the enforcement of the regulations, states have indicated various regulatory actions that are taken such as the suspension of licenses, the issuance of various orders and the actual closure of an x-ray department.

Question 4. Do the various states have adequate resources to assure reasonable compliance with these regulations?

Answer. The answer to this question depends upon the state being questioned. A few states feel that they have adequate resources to assure compliance with the regulations. However, a great majority of the state radiation control programs do not feel they have adequate resources to carry out all the things which they feel should be done. Specifically, it appears that where there are limited resources, the regulatory programs are concentrating their efforts in a very effective manner on prioritized items which have the greatest significance for unnecessary exposure to the population, but only limited attention is being paid to areas of low priority which, if resources were available, the entire spectrum of regulatory control could be implemented. For clarification, some of these areas of low priority are significant in the reduction of unnecessary exposure of our population.

Question 5. Please provide more detail on what form of control of non-ionizing sources exist at the state level.

Answer. Again, the type of control of non-ionizing sources depends on the state being considered. Although several states have enabling legislation allowing for the adoption of regulations in the non-ionizing area, only a few have actually adopted regulations under this legislative authority. This is a specific example in which states have considered the application of their resources to areas in which the exposure of the population is greater, specifically, ionizing radiation, in lieu of expenditures in the non-ionizing area. One state does require the registration of all laser sources and the reporting of any overexposures from lasers which might occur. Although most states do not have regulations in the non-ionizing area, most states conduct some type of inspectional program, primarily on a request basis, of non-ionizing sources, especially microwave cooking ovens. In addition, at least one state has conducted a rather extensive study of the potential exposure in teaching institutions from the use of laser systems. Following that intensive study, a concentrated educational program was used to advise the users in those institutions on the safe use of laser systems. It should be mentioned, that as it relates to protection of the worker, several states do have regulations protecting the worker from non-ionizing radiation which, in most cases, is within the State Department of Labor.

Question 6. Please elaborate on your recommendation for more research in the bio-effects of microwave and radar frequencies.

Answer. There is a need for the establishment of population exposure limits for both microwave and radar frequencies. Such limits exist in the ionizing area and certainly appear appropriate in the microwave and radar area, since these frequencies are in constant use throughout the United States.

Question 7. Do you believe that research on the bio-effects of non-ionizing radiation is being conducted by the various federal agencies in a responsible manner and with an adequate level of funding?

Answer. I do not believe that I have all the necessary information to make a judgement in this matter. Specifically, I am not aware of the dollars that are being spent at the federal level on the bio-effects of non-ionizing radiation. I am aware that several federal agencies have conducted, and are continuing to conduct studies on the bio-effects of non-ionizing radiation, and that such research has been coordinated by the Office of Telecommunications Policy. It is my understanding that considerable research has been done in this area, yet no public exposure standards have been developed. One state in response to my questionnaire, indicated that they had referred several cases of abdominal cancer of young men who had worked several years calibrating radar devices for military aircraft, to NIOSH for study.

Question 8. How could research of the bio-effects of non-ionizing radiation be improved?

Answer. I fully support the concept of one agency at the federal level coordinating the various studies that are being conducted in a given area. I believe that through a coordinated effort, the most efficient expenditure of funds will be obtained and a reduction in duplicative efforts will be achieved. Also, through some type of centralized coordination it would be assumed that findings in various investigative research could be tied together as to the overall impact of the total significance of exposure to non-ionizing radiation.

Question 9. Please amplify your comments indicating that medical and industrial users have complied with applicable standards.

Answer. As indicated in answer Number 2, the regulations enforced by the states are primarily based on the Suggested State Regulations and the recommendations of the National Council of Radiation Protection and Measurements. Although, most current state regulations are more stringent than those that existed in 1960, in general, current regulations basically cover the same areas today as were covered in 1960's. Therefore, based on these adopted regulations and the enforcement of these regulations, a majority of states have found that the compliance rate with these regulations is better today than were found when the programs were beginning in the 1960's. One particular area where significant improvement has been made is in the area of collimation. In the 1960's a large percent of x-ray facilities had inadequate collimation. Although today we are still finding facilities that do not meet the requirements of collimation, percentage wise, the amount that does not meet such a collimation standard is low relative to those that were found during the 1960's.

Question 10. Please document your statement about unnecessary radiation exposure emitted by color television.

Answer. In my testimony on this matter of radiation from color television, I was simply using that example as one in which the general population could be exposed to ionizing radiation. This fact was documented both by the Food and Drug Administration and by various states for color television receivers manufactured prior to the adoption of the performance standard by the FDA relating to the manufacturer of television receivers. Since the implementation of this performance standard, it appears that this source of ionizing radiation exposure to the general population has been significantly reduced, and no longer constitutes a public health concern. In 1973 and 1974 one state did an extensive survey of the exposure to the population from color and black and white television sets, and of the number of sets studies, only one percent indicated any radiation problems.

Question 11. Are T.V. sets currently being sold emitting x-radiation?

Answer. Many electronic devices during their operation will emit electromagnetic radiation. Therefore, it would not technically be correct to say that T.V. sets are not emitting x-radiation at all. The question is the level. Several states have performed some surveys on the emission of x-rays from color television sets since the implementation of the Federal Performance standard and their findings have indicated that most of the units are well within the limits. It is the opinion of most state radiation control programs that television sets which are manufactured under the Performance Standard no longer represent a public health problem as it relates to the emission of x-rays.

Question 12. How is the general public exposed to lasers?

Answer. Laser systems are finding many uses in the areas of construction, communications, and to a more limited use in the medical area. Most teaching institutions, both at the college and high school level use laser systems for various studies and demonstration purposes. Additionally, laser systems can be acquired by individuals for private ownership and use in their homes. However, it appears that the greatest potential for exposure of the general public to laser radiation is in the entertainment field, such as rock concerts, in which laser systems are used to project unusual color designs for visual effects.

Question 13. With respect to your discussion of jurisdictional overlap among Federal agencies, are jurisdictional lines really unclear or is this regulatory maze merely cumbersome?

Answer. It appears that the jurisdictional lines are *both* unclear, and cumbersome to get through. As indicated in my testimony as it relates to the setting of exposure guidelines for medical x-ray, there appears to be confusion as to the jurisdictional lines between the EPA and the FDA. As related to the cumbersomeness of getting through the regulatory maze at the federal level, the statement that was made by one state adequately describes the problem. The statement was, "It is difficult enough to remember all the names without trying to determine the purpose of input of each group involved in emergency planning." One of the problems which may be causing the cumbersomeness in emergency planning is that there is no clear statutory mandate as to which agency should "carry the ball." As an example, EPA has developed guidelines for taking protective actions, but these guides have not been published in the Federal Register. As a result, states are unsure that all federal agencies will support the use of these guidelines.

Additionally, as mentioned in my testimony, the states are concerned about the non-uniform regulation of naturally occurring and accelerator produced radioactive materials. Again, at the federal level, there appears to be at least three agencies involved (NRC, FDA and EPA), but still no regulatory control of this type material in a uniform manner as is now being done with by-product materials.

Question 14. Please provide your opinion of the adequacy of federal guidance on medical x-ray use and emergency radiation plans.

Answer. In general, most states feel that excellent guidance has been provided to the states in the medical x-ray use through the Bureau of Radiological Health of the FDA. In particular states found that federal guidance given through training programs to states has been invaluable. Unfortunately, the availability of these excellent medical x-ray courses presented by the Federal Government have been substantially reduced and most states have identified this void of training as a problem. The Bureau has just recently provided state radiation control programs with a new technique for obtaining training. Specifically, a video player and monitoring system. State radiation control programs applaud the Bureau for this effort as one mechanism that may fill the strongly needed training gap in the medical x-ray area.

As it relates to the emergency radiation plans, I believe that most states feel that the Federal Government is truly trying to provide guidance in this area, but the guidance which is being presented to the states seems somewhat confusing and cumbersome. It would appear that a more direct simple approach of guidance in the emergency planning area would be more effective in the development of state radiation emergency plans, than is now being provided at the federal level. Some efforts are being made to simplify the system, such as the reduction in the items of NRC concurrence for a state plan, but there is still much which could be done to make the process clear and simple.

Question 15. What is the current status of state emergency radiation plans?

Answer. Again, this question has to relate to the specific state under review. Most states have a radiation emergency plan but the status of that plan varies as to its comprehensiveness depending on many factors such as the existance of fixed nuclear facilities within that state, and the availability of resources for the preparation or amendment of such plans.

Question 16. Are the states capable of responding adequately to a major radiation release?

Answer. This is another question which can only be answered as it relates to the specific states under consideration. Specifically, while some states feel that their plans and resources for responding to a major release are adequate to protect the public health and safety, most states have indicated that should a major release occur in which there was wide spread contamination, some assistance would have to be obtained from the Federal Government. Again, this capability of response relates primarily to that of resources. Efforts are being made at the federal level to train state personnel for responding to radiation emergencies. Specifically, the NRC sponsored courses in this area are extremely valuable to the states, and we can only encourage more such courses.

Question 17. What state problems are likely to arise from the storage of high level radioactive waste?

Answer. The establishment of high level waste repositories may necessitate the additional burden on a state, both financially and in manpower, to monitor such facilities to assure the health and safety of its citizens. Specifically, it may be necessary for a state in which a repository is located to establish monitoring wells on the peripheral of such sites which would require routine sampling and analyses by state personnel. Another problem identified is that there may also be associated with a repository above ground solidification or calcination beds. Therefore, in addition to the repository, there may be above ground processes which represent a potential for contamination of the environment.

Question 18. To what extent are the states involved in discussions with the Federal Government on this issue?

Answer. With the recent workshops established by the Office of State Programs in the Nuclear Regulatory Commission, specifically designed to discuss high level waste repositories with state personnel, most state radiation control programs feel that adequate opportunities are being provided for discussions of the issue. However; when a specific state has been identified as a potential state for siting of such a repository much more direct communication between state agency and the Federal Government must occur, and it would appear that the Federal Government is making efforts for this close communication.

Question 19. What major problems do you foresee with respect to proposals requiring the licensing of radiologic technicians?

Answer. There is no conclusive data available to indicate that licensure will engender serious inflation of radiological cost nor deprivation of radiological health services through licensure of radiologic technologists. For example, in a 1976 report to the legislature, the state of California concluded that its licensure program had "been successful in protecting the health of the public by education and training of operators in techniques to reduce unnecessary ionizing radiation." That report further asserted that no manpower shortage resulted from the licensing efforts. Also, in 1976 the American College of Radiology and The American Society of Radiologic Technologists issued a jointly prepared study which found that "mandatory licensure laws created no significant effect upon technological manpower in terms of recruitment, availability, and compensation in three states," and there were "no significant changes in the availability of delivery of radiological services." If there is a major barrier in this area of licensure of radiologic technologists, it would appear that the barrier is that of the acceptability of the licensing of these paramedical individuals by the medical community. There appears to be somewhat of a disagreement in the medical community as to the need for this licensing effort. Some states have been reluctant to institute licensure programs because of confusion over what benefits licensing has produced in terms of actual patient exposure reduction, and over what are considered to be the key elements which should comprise an effective licensure program. Leadership at the federal level has been sorely lacking in this area. We do understand that the FDA, pursuant to the recommendations issued in a recently released HEW report on Health Manpower Credentialing, is planning to begin an effort to develop voluntary recommendations relating to the qualification and credentialing of medical radiation personnel. While we applaud this endeavor, we feel it falls short of the goal of assuring that every operator is adequately trained and proven competent because of its inability to insure adoption and compliance with the recommendations on a national basis.

In respect to the training of persons using medical x-ray, I would like to express another concern of the states which has also been expressed at the federal level. Specifically, as reported in the Bureau of Radiological Health staff report entitled "Diagnostic Medical X-Ray Technologists: The Issue of Qualifications," dated January 19, 1975, "With the exception of 13,000 radiologists, who are expert in the use of radiation for diagnostic and therapeutic purposes, physicians are generally not trained in the principals and practices of radiation protection, and what radiologic training the non-radiologists physician does receive, either in medical school courses or during the clerkship or internship periods, is almost entirely concerned with part of physicians is particularly significant in view of the fact that the performance of the examination is largely delegated by physicians to more than 100,000 x-ray machine operators, many of whom do not possess formal credentials certifying their competence. The situation in many instances, then, is that of a supervisor untrained in radiation protection directing an equally untrained employee."

Although not directly related to the question, I feel a comment must be made again relating to the nonefficacious use of x-ray sources. The states strongly urge that the medical community establish better guidance for "when x-rays are needed."

Question 20. What percentage of "old" x-ray equipment (manufactured or assembled prior to promulgation of the FDA standard) should be inspected each year to insure that both workers and patients are adequately protected?

Answer. The frequency of inspections of x-ray equipment, whether it be old or new equipment, varies from state to state. As an example, many states do not differentiate between the age of equipment in respect to the need for inspections. Rather than depend upon the age as a priority for inspection, many states have established a priority of inspection based on facilities with high work loads, which receive more frequent inspections. As it relates to protection of the patient, the category of hospitals ranks high in inspections, primarily because of the number of patients being exposed, and therefore, having a more significant impact on the total public health. On the other hand, other states have found that they are able to inspect all x-ray facilities on a three year cycle again, regardless of the age of the equipment. Several states now have a contact with the FDA for the inspection of new x-ray equipment manufacture under the FDA Federal Performance Standard. In most cases, this type of inspection is over and beyond their routine inspection of x-ray equipment not under the Federal Performance Standard. As a general statement, most states with an x-ray inspectional program, do not distinguish between the age of equipment in their priorities of inspection. Priorities are based more on the potential for exposure of a large population, and old equipment receives the same type inspection as new equipment. In your letter you mention that "at present industry sources are inspected only once every five or six years." This five or six year inspection frequency may be accurate for industrial x-ray sources with very low potential for exposure of the worker, such as gauges. However, for those industrial x-ray sources which do represent a higher potential of exposure of the worker, for example industrial radiography, these type industrial x-ray sources are inspected, on an average, more frequently than the five or six year average stated in your letter. Some states inspect these type sources annually.

Question 21. Do you believe that microwave cooking oven standards set by FDA are adequate to protect the public health?

Answer. With the present knowledge of the bio-effects of microwave radiation, it is the general consensus of the states which responded to my questionnaire that the FDA standard is adequate. When one considers the normal distance that a person stands when operating such an oven and the occupancy time around such an oven, emission level provided by the standard is adequate. The actual exposure would be quite low and consistent with the exposure level developed by the Russians.

Question 22. Have you noted any efforts on the parts of governmental entities or manufacturers to make sure that consumers understand the potential hazards of products using nonionizing radiation?

Answer. Though efforts have been made at the Federal, State and local levels to educate the consumer relative to the hazards of microwaves, there probably has not been enough effort to make the general consumer completely comfortable with a microwave oven. Examples of the efforts which have been made include several pamphlets on microwave oven safety developed both by the FDA and some states. Of state activity in educational efforts, I have enclosed a copy of a publication by the State of Illinois which has received very wide distribution, not only in the United States but worldwide.

We also understand that FDA's Bureau of Radiological Health has, and is continuing to expand its information efforts utilizing the agency's consumer affairs personnel which are strategically located throughout the U.S. to respond to consumer inquiries concerning microwave ovens.

Question 23. When will the Federal/State task forces issue their final reports?

Answer. While many of the issues identified for task force work within the Conference may require two or three years for final results, the majority of the charges given these task forces are completed within one year. At least a major portion of the charges are expected to be dealt with during the year in which the assignments are made, and a report of their progress is required at the annual meeting of the Conference.

I would like to indicate that many of the above questions were based on my survey of approximately 40 percent of the state radiation control programs which responded to my questionnaire.

Again, I would like to thank you for the opportunity to clarify some of the points made in my testimony, and hope that the above information will be helpful.

Yours very truly,

CHARLES M. HARDIN,
Member, Conference of Radiation Control Program Directors.

Senator STEVENSON. Our next witnesses are Dr. Richard Setlow and Dr. Alvin Lazen representing the National Academy of Sciences.

Thank you, gentlemen, for joining us. You are welcome to summarize your statement if you would like.

STATEMENT OF RICHARD SETLOW, SENIOR SCIENTIST, BROOKHAVEN NATIONAL LABORATORY, UPTON, N.Y.; ACCOMPANIED BY ALVIN G. LAZEN, ASSOCIATE EXECUTIVE DIRECTOR, ASSEMBLY OF LIFE SCIENCES, NATIONAL ACADEMY OF SCIENCES

Dr. SETLOW. I shall read the statement.

Mr. Chairman, Senator Schmitt, I am pleased to appear before your committee in response to your invitation to the National Academy of Sciences for views on a proposal to have the Academy conduct a comprehensive study of the current state of knowledge of the health effects of nonionizing radiation. Such a proposed study also would encompass the suitability of existing standards for this form of radiation, as well as the need to anticipate and prepare for protection against radiation emitted by emerging technologies.

For purposes of identification, I am Dr. Richard Setlow, a biophysicist at Brookhaven National Laboratory, and a member of the National Academy of Sciences. One of my research interests is the biological effects of nonionizing radiation. Accompanying me is Dr. Alvin G. Lazen, the associate executive director of the Assembly of Life Sciences within the National Academy of Sciences.

I believe it would be useful to begin with a background summary on the role of the National Research Council and the some 7,400 scientists, engineers, and other specialists who serve on its 940 committees and subcommittees, panels, boards, and other ad hoc groups.

The Academy's congressional charter, under which the NRC operates, directs the Academy to "investigate, examine, experiment, and report upon any subject of science or art" whenever called upon by any department of the Government. The Academy has been engaged in such studies on behalf of the Federal Government for over 100 years.

Our most recent endeavors include such wide-ranging subjects as the relationship of air quality and health, how can research increase food production, how accurate are our estimates of national and worldwide mineral reserves, in what manner shall we meet energy demands of future generations, what are the effects of halogenated hydrocarbons on the concentration of ozone in the stratosphere, et cetera.

I should add that a number of the more significant studies have been statutorily mandated by the Congress, while others are undertaken upon the initiative of the executive branch. Thus, as you will note, the pending proposal for a study by the NRC of nonionizing radiation is a well-established approach for providing information and recommendation to the Federal Government on program matter with a high technological content.

Next I should list for you the past studies that have been performed by the National Research Council that are related to the subject of your present inquiry.

Studies have been carried out on the effects of microwaves on samples of Korean war Navy veterans who were exposed to microwaves in the form of radar. Reports on these studies were published in 1963 and in 1977. We have also reviewed the U.S. Navy's research program in nonionizing radiation and issued a report which both evaluated the ongoing research and suggested new directions for research for the Navy to perform in the field of both extreme-low-frequency and microwave radiation. At the moment we are about to transmit to the Navy a committee report on the "Biologic Effects of Electric and Magnetic Fields Associated with Proposed Project Seafarer," the antenna system proposed by the Navy for installation in the upper Michigan peninsula.

Late last year the National Aeronautics and Space Administration asked the Academy to perform an assessment of a research plan to determine the biological and ecological effects of energy transmission by microwaves, the research plan to be developed by outside experts under NASA sponsorship. The NASA request was considered by the appropriate NRC bodies and it was decided that a survey of broader scope and an assessment culminating in recommendations for future research should be performed. The broadened proposal includes all aspects of the biological effects of nonionizing radiation, including the effects of microwaves, but excluding visible light and the infrared range.

Based on an approval and authorization by the governing board of the National Research Council, a draft contract proposal outlining such a broad study was prepared and has been discussed with a number of Federal agencies, including the Office of Telecommunications Policy, the Environmental Protection Agency, the Departments of the Army, Navy, and Air Force, the Occupational Safety and Health Administration, and the Bureau of Radiological Health of the Food and Drug Administration. Other Federal agencies with an interest in nonionizing radiation exposure will also be contacted.

Several months ago, we were made aware that the Senate Committee on Commerce, Science, and Transportation, in reviewing the Radiological Control for Safety and Health Act of 1968, was considering mandating a study by the Academy on the biological effects of nonionizing radiation. Let me here explain that the Academy takes no position on the question of whether Congress should or should not specify the National Academy of Sciences to perform scientific assessments; however, it is the usual practice of the Academy when so mandated to negotiate a mutually acceptable contract with the appropriate Federal agency to perform a study.

The Academy study as currently conceived consists of two parts focusing on the biological effects of nonionizing radiation. The first part is a committee study. The Academy performs its studies by inviting experts in the field to accept appointment to a committee which addresses each specific question. The Committee on Biosphere Effects of Nonionizing Radiation will consist of a steering committee representative of the disciplines required to perform an effective study. For instance, we expect to have biologists, psychologists, engineers, physicists, and other appropriate persons. A number of subcommittees will be appointed, each to address itself to a specific part of the question. For instance, we will have a committee on mutagenic and developmental effects of microwaves, one on the effects of microwaves on behavior, one on effects on brain function, et cetera.

In the course of the study, the committee will call consultants to provide it with additional information, and the committee may hold public meetings, workshops, or symposia aimed toward gathering information from the widest spectrum of the scientific and lay communities. At the completion of the committee's deliberations, a report will be prepared that will include three major sections. In the first, the committee will arrive at conclusions, insofar as the availability of data will permit, regarding the biological effects of microwaves and other nonionizing radiation. In the second section, it will make recommendations, insofar as possible, to serve as a basis for safety guidelines for human populations. In the third section, it will identify those areas in which critical scientific information is lacking and thereupon recommend a research program by which that information may be obtained.

The second part of the proposal provides for a continuation and intensification of the epidemiological study on 20,000 Navy veterans of the Korean war exposed to microwaves as compared to 20,000 Navy veterans not so exposed. The epidemiological work just completed has been a study of the causes of mortality of the Navy veterans so exposed. Because microwave effects may be transient in nature, it is essential that the life history of illness be traced from the time of exposure to the present for those veterans who survive. A study on such a large sample of persons has not as yet been performed, and the remarkable resources available to the Academy in its medical followup agency are the best available to perform this study.

In your letter inviting the Academy to express its views concerning a congressionally mandated study, you have also asked whether the Academy might examine emerging technologies which may utilize radiation and the need to anticipate and prepare for protection against radiation emitted by these new technologies. Our current draft proposal does not provide for such a study. However, the subject matter is amenable to examination and could be addressed by an Academy committee. I should mentioned that the Academy is also developing a proposal to study the impact on the over-the-air communications systems and on other microwave-utilizing systems that would result from taking regulatory action on nonionizing radiation. The study can be performed in an interactive manner with the biological effects study.

Mr. Chairman, you have also requested the National Academy view of the suitability of existing standards for nonionizing radiation. The Academy speaks via published reports emanating from its appointed committees. Since no committee has yet reported relative to the suitability of existing standards, there is not yet an Academy view. However, I will be happy to present my personal view of the existing standards, should you so request.

Dr. Lazen and I thank you for this opportunity to respond to your request to present the Academy's views.

Senator SCHMITT [presiding]. Thank you, Doctor. We appreciate your testimony very much.

I would request that you present your personal view.

Dr. SETLOW. My personal view is that we know comparatively little about the long-range effects of microwave radiation on people and that this is a very difficult subject, more difficult than the long-range effects of ionizing radiation on people.

Senator SCHMITT. Would you like to explain why you perceive that difference in difficulties?

Dr. SETLOW. One of the big difficulties is technical. In the ionizing radiation field we have dosimeters. It took many years to get such devices that you could put out in the air and measure the radiation dose someone was exposed to.

These are not conventionally available for microwaves. Certainly biologists do not have ready access to such instruments, nor do we have personal dosimeters. People that work in the field of ionizing radiation, for example, usually carry badges. There are no such things for microwaves.

Trying to assess the exposure of the population to microwaves is a very crude average. We don't know how various peoples vary from that average, even if we knew the average. That is one difficulty.

The second is the effects of nonionizing radiation are much smaller per unit of dose, whatever that is, than ionizing radiation. In particular, the effects on simple molecules and simple cells are much more difficult to perceive than from ionizing radiation.

Therefore, we don't have a background of basic biology, if I could call it that, which enables us to extrapolate theoretically to large-scale systems, so we are forced to rely on experiments on animals and to collect what epidemiological data we can on people. We can't do the experiments on people. Even if we could do such experiments, they would probably be very poor ones. We are a very varied group of individuals and we react in different ways. We have very little background information to permit extrapolations.

Yet there doesn't seem to be any tremendous hazard, as far as one could perceive, from short-term studies at the present time.

My personal view is sort of semiconservative. I would adopt for the time being the present standard for occupational hazard and lower, certainly, the standard for people in general. I would worry about devices that get into homes; how are they going to be observed? How are you going to find out whether such devices really stay as they were first manufactured and not produce more radiation?

This is a different field than ionizing radiation. We don't have individual X-ray machines in houses. We don't sell them normally to people and say this machine is OK; I will come back in 10 years and check it. We don't have that sort of thing. We do for microwaves and other kinds of radiation. That is why I think the standard for the population as a whole has to be lowered—because we have no way of checking up really on the population as a whole.

Senator SCHMITT. By a factor of 10, or 100?

Dr. SETLOW. I would lower it by a factor of 10, subject to the notion that when one accumulates as much data as one has, one might want to lower it by a factor of 10 or raise it a factor of 10, or leave it there.

What I am really saying is, the data are very poor. While there's no good evidence that there's a bad effect at the moment, I don't want to be put in the position of saying there never will be a bad effect.

Senator SCHMITT. Are you suggesting that the initial thrust of research should be in the development of a technology to do further research, or do they have to go hand in hand?

Dr. SETLOW. I think they have to go hand in hand. As I stated, we cannot do the experiments on people. We must extrapolate to people from animal studies, using what little epidemiological data there are, such as the veterans of the Korean war.

In making such an extrapolation, however, from mouse to man, you really have to have a theory to base that extrapolation on. The theory, unfortunately, does not exist at the moment. That's why we have to learn more about what happens in the interaction of such radiation with cells and animals, or really groups of cells, before we can make such an extrapolation.

It's no good, however, doing such experiments unless you can measure how much radiation things are exposed to. It's no good having a good biological experiment and a lousy physical experiment. They both have to go together. There has to be a good impedance match between the two. There's no sense being precise about the radiation dose if we are very imprecise about the biology, and vice versa.

Senator SCHMITT. Would you expect trace components and trace elements to have a larger effect in biological processes relative to the interaction of nonionizing radiation than they do relative to the interaction of ionizing radiation?

Dr. SETLOW. My intuition—that is all it is—would say trace elements would have a rather negligible role to play in the interaction of nonionizing radiation, microwave radiation. They might have a small but appreciable role for something such as ionizing radiation.

Senator SCHMITT. Mr. Chairman, do you have any questions?

Senator STEVENSON. I am sorry I had to step out.

Do you have concerns about microwave ovens? Quite a number—36,000—were recalled recently by one manufacturer.

Dr. SETLOW. I have no direct knowledge. I do have concerns. My concerns are in the form that there is no easy way of checking up on such ovens once they have been installed in the home and used for an appreciable period of time.

Senator STEVENSON. You said that. But why? Why wouldn't it be easy to check a thousand microwave ovens in use and compare that to a couple thousand color television sets? That could be done after a few years to give a good average picture.

Dr. SETLOW. I think there is a fundamental difference. I think we know a great deal about what happens to color television sets, and usually the radiation level doesn't go up in those after construction. If they deteriorate, maybe they just don't work.

If a microwave oven has a slight defective gasket or something of that sort, as a function of time, the amount of radiation coming out of the container could go up. No one has an easy instrument to make a quick survey of that oven in a particular home. That's my concern.

Senator STEVENSON. In a particular home. It wouldn't be too difficult to——

Dr. SETLOW. To make a sample? Not at all. Easy to make a sample.

Suppose 10 percent of the ovens——

Senator STEVENSON. Are leaking?

Dr. SETLOW [continuing]. Are leaking; what do you do? That's my concern.

Senator STEVENSON. I think it would tell you something about the 90 percent.

Dr. SETLOW. That's my concern. What do you do? What do you do with the information?

Senator STEVENSON. What should you be able to do?

Dr. SETLOW. As I say, that's only a concern. That's not an overriding concern.

I think we have really—you know, part of the concern really arises because we have no good notion as to precisely how dangerous such things are. If we are close to the threshold—if there is a threshold—then we would be concerned about leakage. If we are far from the threshold of damage, then we are not concerned.

That is why I think we really need information, quantitative information.

Senator STEVENSON. Aren't you telling the committee that the Academy is well on its way to conducting a comprehensive study of all the current knowledge with respect to the biological effects of nonionizing radiation? Are you saying that?

Dr. SETLOW. I don't think so.

Dr. LAZEN. No. We are planning such a study. We have not begun the study. We are currently taking a draft proposal to various Federal agencies to touch base with them and find out if they are interested in having the Academy perform such a study.

Senator STEVENSON. This study would be a study of all the studies?

Dr. LAZEN. It would review and evaluate all of the available data as a first step.

Senator STEVENSON. Toward?

Dr. LAZEN. Toward next determining what can be learned from that data to set a safety standard; to advise these Federal agencies about what a safe level might be; and, most important, to recommend what research is needed if not enough research has as yet been performed.

Senator STEVENSON. I don't mean to be facetious, but how long would it take to conduct that study of all the studies to determine what studies are needed.

Dr. LAZEN. It's often been said the Academy keeps time by the calendar, rather than by the watch.

Academy studies do take some time. We predict this one would take 2 years to perform.

Senator STEVENSON. How much would it cost?

Dr. LAZEN. There are two parts to the study. One part is a committee study, which would give you the answers that you have just spoken about. It would be a $400,000 study over 2 years.

Another part to the study would make use of a unique Academy resource: The availability of the medical data of the Department of

Defense and the Veterans' Administration. Those data can be used to perform an epidemiological study of Korean war veterans exposed to radar. The purpose would be to try to determine whether their exposure to microwaves has had some health impact.

That part of the study would cost approximately $500,000.

Senator STEVENSON. How could we in the Congress move this process along? Is additional funding necessary? Is a congressional mandate necessary?

Dr. LAZEN. We would hope that our process of touching bases with the various Federal agencies would elicit enough interest from them that they would be willing to support such a study.

If, however, Congress mandates a study, it certainly facilitates matters.

Senator STEVENSON. Should that mandate include additional funding or do you think the funds are already available?

Dr. LAZEN. There are several new topics that have been introduced in the course of discussion.

The letter from Senator Magnuson requesting views from the Academy mentions a study of emerging technologies and the potential health effects of these emerging technologies.

That part is not included in our draft proposal.

It would require additional sums of money if that were also to be studied.

Senator STEVENSON. Don't you think that is important? By the time the study of studies is produced, the additional studies could be irrelevant, if it is not aimed at the circumstances at some time in the future.

You are not disagreeing with that?

Dr. SETLOW. I agree with that absolutely.

Senator STEVENSON. So that part of it at least might require funds in addition to those which might otherwise be available?

Dr. LAZEN. That is correct. The study of emerging technologies would be a difficult one. It involves looking into a crystal ball within a crystal ball—looking at emerging technologies and then trying to predict what health effects might result from those.

Senator STEVENSON. Has the Academy made recommendations to the Navy with respect to Project Seafarer?

Dr. LAZEN. Yes. The final report should be available within 1 month. A preliminary report was transmitted to the Navy in November 1976.

Senator STEVENSON. What did the preliminary report say?

Dr. LAZEN. The preliminary report said that along the antenna the effects of the electric fields and the magnetic fields are so small that they probably present no hazard to health. At the ground terminal of that antenna system, there is a higher electric field, and some potential hazard exists.

Senator STEVENSON. At which end?

Dr. LAZEN. At the ground terminal, at the end where the antenna goes deep into the ground.

Dr. SETLOW. And is connected to the Earth.

Senator STEVENSON. The final report will say the same thing?

Dr. LAZEN. The final report will be in line with that. We will know exactly what it will say in a month.

Senator STEVENSON. Have you considered the biological effects on people in the vicinity of the transmitters which transmit the signals to satellites for communications purposes? The receivers would receive a very weak signal, but the transmitters send out a pretty strong signal. Has anybody looked at what those do to people in their vicinity?

Dr. LAZEN. The committee looked at the entire Seafarer system.

Senator STEVENSON. Does that describe the Seafarer system?

Dr. SETLOW. The two systems, Seafarer, and the microwaves we were speaking about, are completely different. The microwaves are very high frequency radiation that is beamed to the satellites, usually via relatively small antennas.

Senator STEVENSON. Excuse me. If I may interrupt on that point. These antennas, transmitters, whatever they are, are not all small. The ones I see are certainly larger——

Dr. SETLOW. I call that small.

Senator SCHMITT. Compared to Seafarer?

Dr. SETLOW. Compared to Seafarer. They are relatively small, the size of this room. That is still relatively small by such constructions.

Seafarer, on the other hand, is low frequency radiation. The frequencies are very close to those used in our powerlines every day, 60 hertz.

In order to radiate such energy, it requires a tremendous antenna or grid of wires. It cannot be focused. You can't build an antenna large enough to focus it. One of the proposed projects encompasses a good portion of the Upper Peninsula of Michigan, for example. That I call large.

The problems of Seafarer and microwaves are completely different electrically and biologically.

The Project Seafarer that has been alluded to is the long wavelength one. Our report on that will be out shortly.

It is difficult to see where one would collect good epidemiological data for this kind of radiation, unless such a project were begun.

That is no reason, of course, to begin it, whereas there are epidemiological data from microwaves, poor as they might be.

The analysis is completely different in these two cases.

They both come under the heading of electromagnetic radiation, but they really are almost as completely different as X-rays and ultraviolet.

Senator STEVENSON. Let's get back to my question. What about the high frequency microwave transmitter for satellite communications? Does that pose a danger to people in its immediate vicinity?

Dr. SETLOW. I don't know, personally.

Senator STEVENSON. Does anybody know?

Dr. LAZEN. We just do not have information on that.

Senator STEVENSON. Nobody does.

Dr. SETLOW. If there were big effects, they would have been observed. The problem in all this work is what about small effects? All one can say is no large effect.

Senator STEVENSON. Are the effects of nonionizing radiation cumulative?

Dr. SETLOW. No good data. If I can interject, that really depends on the mechanism of what the effects are, whether one can make such an extrapolation. Unless we know that, we can't really make that extrapolation.

Senator STEVENSON. We have a rollcall now.

Senator Schmitt, any questions?

Senator SCHMITT. Very quickly, in the National Academy's defense, I think it would be useful if you would explain in a minute or two how you put together your study teams. I think it is important to realize that you are drawing people from the scientific community who are being paid to do a lot of other jobs besides donating some of their time to the National Academy. A 2-year period for a study is a reasonable length of time in that environment.

As a matter of fact, as I understand it, it is extremely difficult to do a short, quality study utilizing the Academy's resources.

Dr. LAZEN. The committee can be put together in various ways. Let's talk first about the nature of the committee.

In an area where a topic is not very sensitive, where a scientific judgment based on fairly hard data is the topic, one can call upon the recognized experts in that field and ask them to deliberate the question and come up with their best scientific judgment. When study of the subject area involves asking for an evaluation based on a small amount of data and especially if the area is extremely controversial, with the experts at different poles, we sometimes have to form a committee of scientists who are somewhat at a distance from the field itself.

These are statesmen of science, people who can understand the science quite well, but who have not been labeled on one side or the other of the controversy.

Then these people will call in the experts or consultants who will present the information before them.

The statesmen of science then have the opportunity to assess and evaluate what they are hearing and determine what they think is good admissable evidence and what is not.

It is a court of science to some degree. It is not an adversary proceeding, however. It is a scientific investigation.

I would think for the microwave study we might want to use this approach, though it isn't by any means certain. We would want to get statesmen of science on the steering committee at least and have them hear testimony from the experts, those who have performed the actual work.

Now, the method of forming a committee, that is for determining the names of the committee members, we rely first on our Academy members. There are 1,100 members of the National Academy. We ask those persons knowledgeable in the field to recommend to us others who are expert in the field or who might be appropriate for the committee. A list of potential nominees is then gathered, and there are several review steps.

We will be looking for a balanced committee. Therefore, we will go through two or three levels of screening, evaluating the nominees and finally determining in our opinion the best composed committee to address the topic.

Senator SCHMITT. Thank you. I think that clarifies that.

Finally, and even more quickly, do you think there is any danger that, in studying and evaluating the emerging technologies, you will create an environment in which certain emerging technologies may not be pursued? Will you be prematurely discouraging research in the emerging technology?

Dr. SETLOW. No. Not at all. I think one of the goals we would like to achieve is to make long-range predictions of environmental hazards, before it is too late. I think the best example we have had recently is the long-range predictions of depletion in ozone in various technologies. That is really a long-range prediction. It gives us plenty of time to adapt—even though it may seem a little painful at the moment—to adapt to such predictions, so the environment will not be altered drastically. I think that is the goal of these predictions.

Thank you, Mr. Chairman.

Senator STEVENSON. Thank you, Dr. Setlow. The committee will now recess for as long as it takes us to vote.

[The following information was subsequently received for the record:]

QUESTIONS OF THE COMMITTEE AND ANSWERS THERETO

Question 1. The NAS proposed study on the biological effects of non-ionizing radiation was initially stimulated by a NASA request for the Academy to review a research plan "to determine the biological and ecological effects of energy transmission by microwaves . . ." Does the current proposal by the National Academy of Science for a broader study include an examination of the biological and ecological questions that may be raised by a satellite solar power system beaming energy via microwaves? If not, would you consider it feasible to examine these questions in the context of the currently proposed study?

Answer. In the Academy's proposed study, all available data concerning biosphere effects of microwaves will be collected and evaluated. Where necessary information is not available due to a lack of research data, the Committee will recommend research needed to provide the information.

Thus NASA (and other agencies) will be provided with (1) an evaluation of the biological and ecological effects of microwaves whether they originate from the solar satellite or other source and (2) a research plan for filling gaps in the information independently recommended by the Academy Committee, with which the agency may compare its own research plan. We suggest then that NASA's requirement will be met for an examination of the biological and ecological effects attendant upon a satellite solar power system beaming energy to earth via microwaves.

Question 2. Please provide the Committee a copy of the draft contract proposal on the biological effects of non-ionizing radiation currently being circulated among the agencies.

Answer. I have enclosed a copy of the draft contract proposal used as a starting point for discussions with representatives of EPA, FDA, OTP, OSHA, and DOD. The proposal is now undergoing extensive revision. The epidemiological study will be described in far greater detail in our final proposal. We plan to extend the scope of the proposal to include (1) the question of emerging microwave-employing technologies and their possible biosphere effects and (2) the "impact" study as described under item 3. In so expanding the study, the Assembly of Life Sciences and the Assembly of Engineering will assume joint responsibility for performance of the study in a closely coordinated fashion.

Question 3. In your prepared comments, you state "the academy is also developing a proposal to study the impact on the over the air communications systems and on other microwave utilizing systems that would result in taking regulatory action on non-ionizing radiation." Please provide more detail on this proposed study. What is the current status of this proposal?

Answer. The Assembly of Engineering is planning a two-year study of the impact on existing and future over-the-air telecommunications systems that would result from significant changes in radiation level standards. The scope of the study would include a review of the results of ongoing monitoring efforts; a survey of steps taken by telecommunications system operators and telecommunications equipment manufacturers to comply with existing standards; the identification of those portions of existing telecommunications systems that cannot comply with current standards or would fail to comply if the existing standard were made more stringent; a review of telecommunications technology that could alleviate the radiation problem; the prediction of the steps that would need to be taken so that telecommunications systems portions identified could comply, and an estimation of their cost; and recommendations on federal policies or legislation that may be required. A multidisciplinary panel is envisioned consisting of experts in electrical and electronics engineering, radio and wired telecommunications technology, space communications, military communications, telephone networks, radio broadcasting, television broadcasting, medicine, psychology, and public affairs. A detailed proposal is now being developed by a unit of the Assembly of Engineering.

Question. 4. Epidemiological studies on the Korean War veterans exposed to microwave have been criticized in some quarters as being basically inconclusive because of the lack of sophisticated instrumentation capable of recording the dosages received by the men or the power density of levels to which they were exposed at the time of exposure. Please comment.

Answer. In response to your question concerning criticism of the epidemiological study, it is, of course, true that the dosages received by Korean War Navy veterans are not known. They were not measured at the time, nor would it have been practical to do so. For lack of information on doses, resort has been had to a "Hazard Index" instead. The Hazard Index is constructed for a man by considering when and how long he served on each ship, while each ship, in turn, has been classified according to the power of the radio equipment aboard at different times. The Hazard Index thus measures, not what a man received by way of microwave radiation, but what he might, potentially, have received.

Men whose Hazard Indexes are small almost surely had small doses. On the average, men whose Hazard Indexes are very large can be assumed to have received larger doses than men with small Indexes, even if we cannot specify exactly what the doses were.

Viewing the problem more broadly, it is fair to say that, for much human risk assessment, measures of "dose" will be sadly inadequate when assessed by the standard of an investigator in the laboratory who is able to expose animals to measured doses. This lack of precision is equally true of studies of the effects of diagnostic X-ray and of exposures to noxious chemicals. When health effects are small and difficult to measure, or dramatic but infrequent (as in the induction of leukemia by X-rays), to decide whether there *are* effects on humans requires the study of very large numbers—thousands—of persons over very long periods of time. The only feasible and economic way of conducting such epidemiologic studies is to take advantage of experience which has already occurred.

Under these circumstances, the observer is in no position to control the circumstances of exposure, nor to guarantee a recording of its intensity.

For example, neither Stewart nor MacMahon in examining the relationship between X-rays and leukemia could tell, from records, what dose was received per X-ray in their studies of the effects of radiation on the fetus. Often, they could not tell even how many X-rays had been made. Nevertheless, they obtained clear-cut differences in subsequent childhood cancer rates between the exposed children and those not exposed.

Although it would not be difficult to design a good study of the effects on man of long-term exposure to moderate levels of microwaves, the exercise is impractical because of the expense of performing such a study and the ethical issues involved in experimenting upon humans. Even if carefully measured and documented exposures could be made, one would have to wait several years to ascertain the outcomes, assuming one could succeed in keeping the study subjects under observation.

In brief, the justification for the Korean veteran study is not that it is ideal, but that, at the present time it represents the best that can be done as a practical matter. The choice is, given the imperfections, shall we learn what we can—or shall we simply ignore the problem.

Question 5. Approximately how much additional funding would a study of the emerging technologies and the potential health effects of these emerging technologies require?

Answer. The contract proposal already circulated among several agencies called for a committee study of two years duration of the biological effects of nonionizing radiation at an estimated cost of $400,000 and an epidemiological study, three years and $500,000. The revised and expanded proposal will include the "impact" study, two years and $320,000, and the "emerging technology" study, two years and $250,000.

PROPOSAL FOR REVIEW OF THE BIOLOGICAL EFFECTS OF MICROWAVE AND OTHER NONIONIZING RADIATION

SUMMARY

Devices emitting nonionizing electromagnetic radiation are widely used in public and military applications, such as telecommunications, radar, microwave ovens, diathermy treatment, and electric power transmission. Future use of microwaves is expected to increase dramatically. Yet data concerning the biological effects of microwave and other nonionizing radiation—including radiations, radio telephone systems, CB radios, radar devices and systems, satellite inadequate for the purpose of establishing protection guidelines for populations exposed, and to sources of microwave and other nonionizing radiation, for estimating potential risks to those populations. This project will entail a critical review and evaluation of the existing scientific knowledge on human and laboratory animal exposure to microwave and other nonionizing radiations. The purposes of the project will be to:

Arrive at conclusions regarding the biological effects of microwave and other nonionizing radiation,

Make recommendations insofar as possible to serve as a basis for safety guidelines for human populations, and

Identify those areas in which critical scientific information is lacking and recommend a research program by which that information may be obtained.

ORIGIN

Renewed interest and some concern have emerged regarding the health effects and safety of microwave ovens, extra low-frequency radiation, and nonionizing radiation from power transmissions:

News reports concerning the beaming of microwaves into the American Embassy in the Soviet Union began a series of speculations about potential health hazards to personnel involved. The Department of State has contracted for an epidemiological study to investigate this specific allegation.

A two-part article by Paul Brodeur in The New Yorker, December 1976, has heightened public consciousness of the lack of information and possible hazards associated with exposure to microwave radiation.

Considerable interest and controversy have arisen concerning plans to construct an extremely low-frequency signal transmission system to be used by the U.S. Navy (Project Seafarer). The ALS has studied this issue exhaustively.

The numbers and kinds of sources emitting microwave and other nonionizing radiation are rapidly increasing in this country and elsewhere. Television stations, radio telephone systems, CB radios, radar devices and systems, satellite communications systems, microwave ovens, industrial applications, and power transmission lines are among the sources of nonionizing radiation in wide use. Diathermy and some cauter-and-incision devices make use of the thermal properties of microwave radiation for their medically useful effects. 1970 NIEHS report titled Man's Health and the Environment . . . Some Research Needs states that . . . the widespread use of microwave generators . . . has reached such an extent that one might conservatively estimate that nearly one-half of our population lives in a measurable microwave environment. Increased urbanization will move greater numbers into an energy field which did not exist one hundred years ago (p. 106).

The proliferation of existing as well as future systems that will utilize or produce nonionizing radiation calls for an intensive evaluation of potential hazards to exposed human populations and other biological systems.

The U.S.S.R. and other eastern European countries have reported extensively on non-thermal, low-level effects of microwave radiation. The accepted safety standard in Russia for exposure to microwaves ranges from 100 to 1,000 times less than the standards set in the U.S.

Previous committees of the National Research Council have been involved in this area. In 1963 and 1977, the Medical Follow-Up Agency/ALS reported on the effects on Navy Veterans exposed to radar emissions during the Korean War. This study is the most comprehensive epidemiological work performed on humans exposed to microwave radiation. The study group included about 20,000 Navy veterans exposed to radar who were compared to about 20,000 closely matched Navy veteran controls. An Ad Hoc Committee on the Navy Nonionizing Radiation Research Program/ALS released its report in 1974. The Committee on the Biosphere Effects of Extremely Low-Frequency (ELF) Radiation/ALS is scheduled to release its report to the Navy in mid-1977. Information gathered in this intensive study of the effects of ELF on humans and the ecosystems will be current and useful in fulfilling the task outlined in this proposal. The Assembly of Behavioral and Social Sciences and the Assembly of Engineering have studied or are currently studying ocular effects of microwave radiation and microwaves generated in telecommunications.

In September 1976, the National Aeronautics and Space Administration (NASA) requested the ALS to review the research priorities set by NASA for studying biological effects of microwave radiation as they relate to the solar energy satellite program.

Public Law 90–602, "Radiation Control for Health and Safety Act of 1968," is scheduled for Congressional review and possible change. Staff of the Senate Commerce Committee and an analyst in biological sciences for the Congressional Research Service, Library of Congress met with ALS staff members in February 1977 to discuss the possibility that in amending PL 90–602, the Congress may request the National Research Council to conduct a thorough review of the existing knowledge of the health effects of microwaves and other nonionizing radiation.

PROPOSED PLAN OF ACTION

The proposal is envisioned as involving two independent but interrelated parts.

Part 1: A committee will be established that will have the following charge:

Review and assess the existing data on the biological effects of microwave and other nonionizing radiation. The biological effects studied will include evaluation of the somatic, behavioral, and genetic effects determined from observation of humans and predictable from animal models. Evaluation will also be made of the effects on other biological systems such as microbes, plants, and animals. The impact of microwave and other nonionizing radiation on the entire ecosystem also will be assessed.

Determine the research priorities for each of the issues above.

Where information is adequate, provide estimates which may be useful for establishing guides for protection, if necessary.

The Committee membership will include biologists, ecologists, engineers, physicists, medical specialists, geneticists, psychologists, and other scientific disciplines as required.

Panels and subcommittees, each chaired by a member of the Committee and consisting of "outside" consultants and experts, will be formed to address specific issues.

In addition to the regular committee meetings, public meeting(s), symposiums and conferences may be conducted to meet the goals of this project.

Part 2: The epidemiologist study of Navy veterans will be extended and refined.

Evaluation of the effects of environmental insults on human health is notoriously difficult. Despite decades of experience with X-rays, there is still no consensus among informed scientists concerning the risks associated with small doses of X-rays delivered at a slow rate. Experiments with laboratory animals have elicited a variety of biological effects that X-rays can produce, but the characteristic effects vary from species to species, and even from strain to strain among mice and rats: the very shapes of the dose-responsive curves are different between Sprague-Dawley and other kinds of rats.

The problems that are merely difficult with respect to X-rays become nearly impossible when extended to microwaves. Cancer induction, our chief concern in regard to X-rays, is objectively verifiable; cancers are as easily diagnosed in a mouse as in a man. The Russian literature, at least, on microwave effects, speaks of subtle neurological effects much more difficult to assess than cancer induction and the task of risk evaluation becomes, correspondingly, more complex.

For two reasons, then, assessment of risks to humans depends upon the study of humans: We cannot with confidence extrapolate from mouse to man; and man can tell us things about his mood and his performance, whereas animals cannot.

An epidemiological study of morbidity will be performed comparing the exposed group of Navy veterans to the controlled group of Navy veterans.

ANTICIPATED RESULTS

A final report will be prepared in which conclusions are drawn regarding the known and/or potential biological effects of microwave and other nonionizing radiation, focusing on the biological risks to exposed human populations. It is expected that such conclusions will serve as a reliable base upon which reasonable protection guidelines may be established if deemed necessary, including the length and levels of exposure of various populations of chronically and acutely exposed individuals, and performance standards for various electronic products that emit microwaves or other nonionizing radiation. The final report will identify those areas where critical information is lacking and recommend research priorities.

It is anticipated that symposium proceedings resulting from the review will be published as part of this project.

ESTIMATED COST

Part 1 can be accomplished in 24 months at an estimated cost of $400,000. It is estimated that Part 2 of this proposal can be accomplished in 36 months at an estimated cost of $500,000.

The following table shows the proposed schedule of performance and an estimate of costs.

	1st yr	2d yr	3d yr
Pt. 1	$200,000	$200,000	
Pt. 2	120,000	190,000	$190,000
Total yearly cost	320,000	390,000	190,000
Total estimated cost		900,000	

[Recess.]

Senator Stevenson. The committee will come to order. The next witness is Mr. Richard Bauer, president of the American Society of Radiologic Technologists.

Once again if you would prefer to summarize, we would be happy to enter your statement into the record.

STATEMENT OF RICHARD BAUER, R.T., PRESIDENT OF AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS

Mr. Bauer. I have a brief report, Mr. Chairman. I think I will read it, the entire report.

Senator Stevenson. Very well.

Mr. Bauer. Mr. Chairman, members of the committee, my name is Richard Bauer. I am president of the American Society of Radiologic Technologists. We welcome the opportunity to appear before you today during these oversight hearings on radiation health and safety, and we commend the committee for its attention to this very timely subject.

For years the American Society of Radiologic Technologists has expressed its concern regarding unnecessary medical radiation to the patient-consumers of this country. In May of 1968 during consideration of H.R. 10790 (Public Law 90-602) we testified before this committee and stated:

> We can understand the justification for regulation and improved standards if public health is to be adequately protected. . . . The American Society of Radiologic Technologists wishes to make a matter of record the firm conviction of all its members that patient exposure should be reduced to the absolute minimum necessary to provide appropriate diagnostic information.

Enactment of the Radiation Health and Safety Act of 1968 has given impetus to the reduction of unnecessary medical radiation by the establishment of performance standards for radiologic equipment, but no equipment can be any better than its operator. Any and all radiation emitted by properly calibrated equipment is produced solely at the will of the operator. Radiation is not detected by the senses of sight, hearing, touch, smell or taste. Without sufficient knowledge of its use, the operator has the potential to damage not only the patient's health but his own as well.

Moreover, the patient-consumer is rarely in a position to judge either the qualifications of the operator or the quality of the examination. The use and abuse of radiation is deserving of due consideration. Again, we are encouraged to have this committee share our concern.

Since the enactment of Public Law 90–602, the American Society has gone on record in each succeeding Congress in support of the enactment of Federal minimum standards of education for radiologic technologists. There are currently an estimated 130,000 to 150,000 operators of radiologic equipment in this country. Approximately half of these individuals have voluntarily submitted to examination and have met the educational standards prescribed by the profession. The remaining 50 percent have no officially recognized qualifications.

At the request of the Department of Health, Education, and Welfare, there was a moratorium on the licensing of additional allied health personnel from 1971 to 1975. During these 4 years the subject of credentializing health manpower was studied. In June 1976, a preliminary report was prepared by the Subcommittee on Health Manpower Credentialing of the Public Health Service Manpower Coordinating Committee entitled "A Proposal Credentialing Health Manpower." At that time the Department invited the official reaction of the States and appropriate professional organizations to the recommendations contained in that preliminary report.

Although we understand that the final report on credentialing health manpower may soon become available, its preparation has required an extended period of time. There has been no discernible progress in this important area since the moratorium was first imposed in 1971.

Further, we are satisfied that the implementation of any recommendations with reference to credentialing health manpower will be a very lengthy, time-consuming process. Until this report is released, it is not possible to comment further.

Although there has been no definitive development that we are aware of, it is our understanding that the Environmental Protection Agency is in the process of developing Federal radiation guidelines for diagnostic X-rays to reduce unnecessary radiation exposure of patients, including that caused by inadequate operator preformance. These guidelines, which will apply to Federal agencies when approved, were developed under the authority of the former Federal Radiation Council, the functions of which were transferred to EPA in 1970. These guidelines, which were prepared by an interagency working group of senior medical officials from the military and the Veterans' Administration, were published in the Federal Register of January 26, 1977, page 4884, and are indeed a step in the right direction. We have been told that these guidelines are still in the process of being finalized.

We commend the Federal Government for asserting this much needed leadership, and we are indeed hopeful that these guidelines, several of which relate directly to the qualifications of operators of X-ray equipment, will receive the President's consideration and approval at an early date.

However, as I pointed out, these guidelines, when approved, will be mandated only for Federal facilities using diagnostic X-rays.

In the absence of conclusive action by a Federal agency, the American Society of Radiologic Technologists continues to believe the Federal legislation is the best approach to insure operator competence in the use of X-ray equipment. At present legislation is pending in both the Senate and the House to provide for the protection of the public from unnecessary medical exposure from ionizing radiation.

Mr. Chairman, your committee will be interested to learn that the American Society of Radiologic Technologists at its annual meeting here in Washington last week, which was attended by more than 2,000 members, unanimously adopted resolutions in support of the enactment of S. 1695, the Radiation Health and Safety Act of 1977, introduced in the Senate by Senator Jennings Randolph and, its companion bill in the House, H.R. 4573, introduced by Congressman Edward I. Koch. I would like to request that these resolutions be made a part of the record.

Senator STEVENSON. The resolutions will be entered in the record.

Mr. BAUER. On behalf of the American Society of Radiologic Technologists, I appreciate the interest of the committee in reviewing this important aspect of health care, and will be pleased to respond to any questions the committee may have.

Senator STEVENSON. Thank you, Mr. Bauer.

You say about half of the 130,000 to 150,000 operators of radiologic equipment in the country have met the educational standards prescribed by the profession. I gather from that estimate you don't have a very precise idea of how many operators there are in the country?

Mr. BAUER. No, we do not have a precise estimate.

Senator STEVENSON. The other 50 percent have no officially recognized qualifications. What does that mean? They could be operating this equipment with no appropriate training?

Mr. BAUER. That's right.

I would like to back up just a minute, Mr. Stevenson.

As far as the qualified operators, we have records from the American Registry of Radiologic Technologists. I don't have the figures with me, but there are approximately 60,000 to 65,000 certified by the American Registry of Radiologic Technologists and currently operating in the field. The exact percentage is the thing that I am in question about because we don't know the total number operating in the country.

Senator STEVENSON. What are the bases for your certification?

Mr. BAUER. A minimum of 2 years' education in a program approved by the American Medical Association; and followed by examination by the American Registry of Radiologic Technologists.

Senator STEVENSON. What does the AMA require in the way of education?

Mr. BAUER. Our programs are approved by the AMA. The details within the program?

Senator STEVENSON. What kind of curriculum?

Mr. BAUER. Anatomy, physiology, radiation safety, radiation biology, radiographic positioning, medical ethics, and other appropriate subjects.

Senator STEVENSON. You get that kind of training at medical schools?

Mr. BAUER. These are programs specifically designed for X-ray technologists.

Senator STEVENSON. At accredited medical schools?

Mr. BAUER. The majority of the programs are operated in hospitals approved for that purpose by the AMA. There are some college-based programs in area hospitals.

Senator STEVENSON. Are those who are certified required thereafter to periodically upgrade their training, keep abreast of newly developed equipment and techniques? Are there any postcertification programs?

Mr. BAUER. At the present time, there is no requirement for continuing education; but the American Society has instituted a voluntary program of continuing education for those who wish to document their evidence in continuing education.

Senator STEVENSON. The other 50 percent, there aren't any qualifications at all established?

Mr. BAUER. No qualifications at all, sir.

Senator STEVENSON. Don't one or two States have——

Mr. BAUER. There are, I believe, 12 States that now have licensing laws enacted. Not all of them have been fully implemented so far.

Senator STEVENSON. When those laws were or are implemented, there will be a licensure or certification procedure for all technicians?

Mr. BAUER. Generally speaking, licensed practitioners are exempt from this type of legislation; but anyone who is not a licensed practitioner will be required to have a license in order to expose another human being to ionizing radiation.

Senator STEVENSON. In those States?

Mr. BAUER. In those States.

Senator STEVENSON. How adequate are those testing or licensure procedures in the few States that have them, in your opinion?

Mr. BAUER. There is wide variation in the present licensing laws.

One of the things the American Society is going to take a look at this year is a comparison between these existing licensing laws. We want to draw comparisons, educational requirements, the makeup of the board of examiners, fee structures, continuing education requirements, this sort of thing.

The entire formula has not been developed yet. This is one of the things we will be looking at during the coming year.

Senator STEVENSON. Do you have any more observations to make about the equipment? Is the old X-ray equipment being upgraded, modernized rapidly? What should be done to make sure that it is, if anything, and that it is maintained properly?

Mr. BAUER. Well, I don't think our society is in a position to evaluate that sort of thing.

Senator STEVENSON. It is too technical?

Mr. BAUER. It is a different area. It would be more related to the program directors, the gentlemen who spoke a few moments ago. It would be in their area, rather than within our society.

We discussed back and forth among each other what new equipment is going into this particular hospital. We don't have any scientific data on that.

Senator STEVENSON. Aren't radiologic technologists exposed to radiation depending in part on the quality of the equipment? Wouldn't that be a basis for some concern?

Mr. BAUER. We are concerned about it, but we also are very careful about it. It is an important part of our own education. I am sure every technologist in the country is aware of it, cautious about it; but as I say, I don't know just how this is being done on a national level. It could be an individual effort by the various hospitals, each individual technologist.

Senator STEVENSON. Are technologists monitored periodically? Is there any program to do that, to determine what the cumulative effects of their exposure is?

Mr. BAUER. Yes. As far as I know, every technologist in the country wears a film badge or a detection device of some kind to determine accumulated radiation.

Senator STEVENSON. That is voluntary?

Mr. BAUER. I believe it is mandatory.

Senator STEVENSON. Who would mandate it if it were mandatory?

Mr. BAUER. It may be mandated by the various State boards of health, that's a possibility.

Senator STEVENSON. Thank you, Mr. Bauer. That is very helpful.

If any of the other members have any additional questions, we will take the liberty of asking them of you in writing.

Mr. BAUER. Please do that.

[The documents referred to follow:]

RESOLUTION IN SUPPORT OF SENATE BILL 1695

(Radiation Health & Safety Act of 1977)

Whereas, The American Society of Radiologic Technologists is a national professional organization of radiologic technologists certified by The American Registry of Radiologic Technologists; and

Whereas, the Society perceives the problems inherent in the equitable distribution of health care to persons at all socioeconomic levels in all geographic locations; and

Whereas, the Society appreciates the dangers implicit in exposure of the public from sources of radiation; and

Whereas, since 1968, the Society has supported federal minimum standards of not less than two years of education for operators of medical equipment emitting radiation; and

Whereas, the Society is convened in Washington, D.C., June 17–23 1977, and believes it appropriate to express concern about unnecessary radition exposure of patients caused by operators of equipment who have less than the established standards: therefore,

Be it resolved: That The American Society of Radiologic Technologists continues its pursuit for the enactment of federal minimum standards of education for radiologic technologists; and

Be it further resolved: That the members of this Society go on record in support of S. 1695, as introduced in the ninety-fifth Congress, by the Honorable Jennings Randolph (W. Va.).

RESOLUTION IN SUPPORT OF HOUSE BILL 4573

(Radiation Health & Safety Act of 1977)

Whereas, The American Society of Radiologic Technologists is a national professional organization of radiologic technologists certified by The American Registry of Radiologic Technologists; and

Whereas, the Society perceives the problems inherent in the equitable distribution of health care to persons at all socioeconomic levels in all geographic locations; and

Whereas, the Society appreciates the dangers implicit in exposure of the public from sources of radiation; and

Whereas, since 1968, the Society has supported federal minimum stadards of not less than two years of education for operators of medical equipment emitting radiation; and

Whereas, the Society is convened in Washington, D.C., June 17–23, 1977, and believes it appropriate to express concern about unnecessary radiation exposure to patients caused by operators of equipment who have less than the established educational standards; therefore,

Be it resolved: That The American Society of Radiologic Technologists continues its pursuit for the enactment of federal minimum standards of education for radiologic technologists; and

Be it further resolved: That the members of this Society go on record in support of H.R. 4573, as introduced in the ninety-fifth Congress by the Honorable Edward I. Koch (N.Y.).

[The following information was subsequently received for the record:]

THE AMERICAN SOCIETY OF RADIOLOGIC TECHNOLOGISTS,
Milwaukee, Wis., September 13, 1977.

Hon WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation,
Russell Senate Office Building, Washington, D.C.

DEAR SENATOR MAGNUSON: Thank you for the opportunity to comment further on the question of radiation health and safety. We offer the following responses to your questions:

Question. "We are told that 50 percent of the operators of radiologic equipment in this country do not meet your society's educational standards. Where are such people generally employed? Do major hospitals usually accept these relatively untrained technicians, even in states without licensing requirements? Or are they primarily hired by private practitioners? Do you have any idea of how many patients are treated by trained technicians versus the number exposed to untrained?"

Answer. The approximately 50 percent of the operators of radiologic equipment who do not meet standards espoused by our Society are employed, for the most part, in offices and clinics of physicians, podiatrists, or chiropractors. A few of them still work in hospitals simply because they have worked there for years, but very few, if any, hospitals now hire unqualified operators.

In the office or clinic, the operator of the radiologic equipment is frequently the receptionist, nurse, secretary, file clerk, or (in one outstanding example I heard of) the maintenance man. The "training" these people receive is frequently a few minutes of instruction by the employer on how to turn on the machine and which button to push. Since most medical school curricula do not include courses in the interpretation of radiographs, in radiation safety, or in radiation biology, many of the employers themselves have had little education specifically directed toward the safe use of radiographic procedures, thus are unable to pass along this kind of information to their employees.

We have no accurate figures on the number of patients exposed to radiation by qualified versus unqualified operators. However, it is apparent that there are more pieces of X-ray equipment in private offices and clinics than in hospitals. Thus, while each operator in a private office or clinic may expose fewer patients to radiation, the total number exposed by unqualified operators may approach, or even exceed, the total number exposed by qualified operators. Moreover, the radiation per exposure given to the patient by the unqualified operator is likely to exceed that given by the qualified operator because the unqualified operator may lack knowledge of radiation safety. Finally, the unqualified operator may need to make several exposures before achieving a satisfactory radiograph, again delivering unnecessary radiation to the patient.

Question. "Another problem in the ionizing area is physicians' prescribing of unnecessary X-ray examinations because of the current malpractice climate. We have heard of studies which may help alleviate this problem, such as a study at the University of Washington to determine the criteria for the most efficacious skull X-rays. Can you see any other routes, legislative or otherwise, for correcting this problem?"

Answer. I feel there may be some value in setting a legal limit on the size of malpractice settlements, although I recognize that such legislation may not be possible or desirable from your standpoint. Any legislation which would attempt to define criteria by which X-ray examinations are ordered would infringe upon the medical judgment of the physician. The current malpractice situation, and the resultant increase in radiographic examinations, again emphasize the need for radiologic technologists who can meet minimum standards of education as would be required by The Radiation Health and Safety bills now before both Houses of Congress.

Question. "On page 2 of your prepared comments you state 'we are satisfied that the implementation of any recommendations with reference to credentialling health manpower will be a very lengthy, time-consuming process.' Exactly how long do you envisage, and what factors are likely to be most responsible for any delay?"

Answer. It has been six years since the Department of Health, Education, and Welfare requested the moratorium on the licensing of additional allied health personnel. Since that time, DHEW has been preoccupied with standards for equipment and has virtually ignored the question of standards for the operators of that equipment. Because of this attitude on the part of DHEW, we have no idea how long it may take before credentialling of radiographic equipment operators will be mandated.

The bills before Congress (S-1695 and HR-4573) both provide a year for the Secretary of HEW to develop standards for the licensing of technologists and the accreditation of educational institutions teaching radiologic technology. The bills further provide for a two year period for the states to enact legislation to meet the standards. On the assumption that a "grandfather clause" will be written into any licensing legislation, we expect a minimum of six years before all operators of X-ray equipment will be required to demonstrate qualifications. Any delay in the passage of this legislation will further delay assurance to the patient that his radiographic examination will be conducted by a qualified operator.

Question. "It is our understanding that no authority exists at the present time for regulation of in-use medical and dental X-ray equipment. Is this correct, and if so, is there a need for further regulatory authority in this area? What factors would limit enforcement of such regulations? Do you think that this should be done by the Federal government, or will an attitude of medical self-policing be adequate?"

Answer. The Bureau of Radiological Health and the various states have some regulations concerning in-use X-ray equipment. These regulations relate primarily to the electrical, mechanical, and radiation safety of the equipment, and not to the actual usage of the equipment. Enforcement of these regulations is difficult because of budgetary restraints, manpower, and the large number of radiographic installations. Self-policing is an impractical answer since many of the owners of the equipment are unaware of the problems with radiation exposure and radiation safety.

With insufficient enforcement of present regulations, it would not seem practical to suggest additional regulations. However, some of the items that might be considered include requirements for proper collimation of the primary beam, gonadal shielding, the accounting for repeated exposures, and again, proper education for the operators of the equipment. These should all be adopted on the national level for the sake of uniformity across the country.

Question. "How serious is the problem of radiation exposure of radiologic technologists? To what extent are such persons being routinely monitored for cumulative radiation exposure, and do programs exist for long-term study of health effects in such individuals?"

Answer. I do not believe there is a serious problem of radiation exposure for registered radiologic technologists, since radiation safety is an important part of the curriculum in any approved educational program for technologists.

In spite of OSHA regulations and the various state radiation protection codes, there may be a problem with over-exposure among some of the non-qualified operators due to ignorance of the regulations and the dangers of excess radiation.

I am not aware of any long-term studies now underway to determine the effect of radiation exposure on operators of radiologic equipment.

Again, thank you for the opportunity to comment further on this question.

Sincerely,

RICHARD G. BAUER, R.T. (ASRT),
President.

Senator STEVENSON. Before we adjourn, a brief statement about our plans might be in order. We have accumulated a great deal of testimony. The committee has also received responses from about 30 Federal agencies concerning their programs and policies with regard to ionizing and nonionizing radiation.

The staff will require several weeks to evaluate all of this evidence. Where it appears the Federal agencies are not carrying out their statutory responsibilities satisfactorily, the committee will communicate its findings to the respective agencies. At that time we will announce additional hearings to receive testimony from the agencies on how these inadequacies are being corrected. If discrepancies or contradictions are evident in the testimony, or the committee receives additional material that casts doubt on the testimony we have received, we will recall witnesses to examine such unresolved matters.

We may in the near future have legislative recommendations to make, including, for example, a mandated study of nonionizing radiation with appropriate funding to be conducted by the National Academy.

I am deeply concerned because of what I have heard about the dangers of radiation of all kinds and what appears to be a fragmentary, at best, research effort in nonionizing radiation, a seriously deficient regulatory and enforcement program to protect citizens from all forms of radiation, and the failure to focus research on future emerging problems such as the shift to coal as a source of energy.

These hearings are just the first round of what will be a continuing serious effort by the committee to face up to radiation and all of its consequences and to protect the public.

The hearing is adjourned.

[Whereupon, at 12:52 p.m., the hearing was adjourned.]

ADDITIONAL ARTICLES, LETTERS, AND STATEMENTS

Prior to the hearings the committee sent the following request for information to Federal agencies having research or regulatory responsibilities related to radiation health and safety.

MAY 19, 1977.

DEAR ————:

Since the enactment of the Radiation Control for Health and Safety Act of 1968 (P.L. 90–602), radiation health and safety research and regulation and other associated federal responsibilities have undergone a profound evoluation. In order to examine this area of significant secientific and public concern, the Senate Committee on Commerce, Science and Transportation is planning comprehensive hearings in June to review and evaluate federal radiation research and regulatory programs.

In order that these programs can be readily compared and evaluated, we are requesting that the various federal agencies carrying out radiation regulation or research provide a comprehensive listing and short description of each of their relevant projects or programs utilizing the format of the two enclosed matrices.

If the format of either of the matrices needs to be modified in order to more adequately describe the nature of certain of your programs, we would appreciate it if you would contact Sharon Nelson (224–0411) or Dan Jaffe (224–9345) of the staff of the Senate Commerce, Science and Transportation Committee in order to discuss such alteration and to assure that the information provided will be in a form that maximizes comparability and ease of evaluation.

In addition, we request your written response to the following questions:

(1) What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e. inception of new agencies, transfers of regulatory authority, etc.)? Now how have these changes affected your overall efforts in the radiation area?

(2) Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

(3) Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

(4) What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

If you have any other questions concerning this matter, please contact Sharon Nelson or Dan Jaffe of the Committee staff. Your written response to all the above requests should be provided to the Committee no later than June 6.

Sincerely yours,

ADLAI E. STEVENSON,
Chairman, Science, Technology and Space Subcommittee.
WENDELL H. FORD,
Chairman, Consumer Subcommittee.

IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)												
1969 Extra-Mural (Funds) Total Funds												
1970												
1971												
1972												
1973												
1974												
1975												
1976												
1977												
Est. 1978												

applies to all years

NON-IONIZING RADIATION*

*(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)												
1969 Extra-Mural (Funds) Total Funds												
1970												
1971												
1972												
1973												
1974												
1975												
1976												
1977												
Est. 1978												

applies to all years

Senator STEVENSON. Mr. Chris Dodge, of the Congressional Research Service, Library of Congress, completed the following charts which provide a rough indication of the categories in which Federal research, regulatory, and development programs fall.

GENERAL OVERLAP OF FEDERAL RESEARCH, REGULATORY, AND DEVELOPMENT—PROGRAMS CONCERNED WITH NONIONIZING RADIATION

Year	1	2	3	4	5	6	7	8	9	10	11
1968	Navy, AF, NIH, ARPA, Army.	Navy	AF, Army	NIOSH, AF, FCC, Army, OTP.	AF	FAA, NIOSH, AF, NIH, Army.	NIH, Army		Navy	Navy, AF, Army	NBS, Army.
1969	Navy, AF, NIH, ARPA, FDA, Army.	do	MESA, AF, FDA, Army.	NIOSH, Navy, MESA, AF, FCC, FDA, Army, OTP.	MESA, AF	do	do	MESA	do	Navy, AF, Army, FDA.	Do.
1970	do	do	do	do	MESA, AF, FDA.	FAA, AF, NIH, FDA, Army.	do	MESA	do	do	NBS, FDA, Army.
1971	do	do	OSHA, MESA, AF, Army.	Navy, MESA, AF, FCC, FDA, OTP Army.	MESA, AF ,FDA.	do	do	MESA	do	do	NBS, FDA, Navy, Army.
1972	Navy, AF, NIH, EPA, FDA, DNA/AFFRI.	do	OSHA, NIOSH, NBS, MESA, AF, Army.	NIOSH, Navy, MESA, AF, FCC, FDA, OTP, Army.	MESA, AF, FDA.	FAA, NIOSH, Navy, AF, NIH, Army.	do	MESA	do	Navy, AF, Army, FDA, DNA-AFRRI	NBS, FDA, VA, Navy, Army.
1973	Navy, AF, NIH, EPA, FDA, DNA-AFRRI, Army.	do	OSHA, NBS, MESA, AF, FDA, Army.	do	MESA, AF, FDA.	FAA, NIOSH, Navy, AF, NIH, FCC, Army.	do	FAA, Navy, MESA, EPA.	Navy, EPA	do	NBS, VA, Army, Navy.
1974	NIOSH, Navy, AF, NIH, EPA, FDA, DNA-AFRRI, Army.	do	do	NIOSH, OSHA, Navy, MESA, AF, FCC, FDA, Army.	OSHA, MESA, AF, FDA.	FAA, NIOSH, OSHA, Navy, AF, NIH, FCC, Army.	do	MESA, EPA, Navy, FAA.	NBS, EPA, Navy.	do	NBS, FDA, VA, FAA, Navy, Army.
1975	do	do	do	NIOSH, OSHA, Navy, MESA, AF, FCC, OTP, Army.	OSHA, MESA, AF, FDA.	FAA, NIOSH, OSHA, Navy, AF, NIH, FCC, FDA, Army.	do	FAA, Navy, MESA, EPA.	Navy, NBS, EPAl	do	Navy, NBS, VA, FDA, Army.
1976	NIOSH, Navy, AF, NIH, VA, EPA, FDA, DNA-AFRII, Army.	do	do	NIOSH, OSHA, Navy, MESA, AF, FCC, FDA, OTP, Army.	OSHA, MESA, AF, FDA.	do	NIA, VA, Army.	Navy, MESA	Navy, NBS, EPA.	do	Do.
1977	do	do	do	do	OSHA, MESA, AF, FDA.	FAA, NIOSH, OSHA, Navy, AF, NIH, VA, FCC, FDA, Army.	do	MESA	Navy, NBS, EPA, Army.	do	NBS, VA, Navy, FDA.
1978	FAA, NIOSH, AF, NIH, VA, EPA, FDA, DNA-AFRII, Army.	do	do	do	MESA, AF, FDA.	NIOSH, OSHA, FAA, Navy, AF, NIH, VA, FCC, FDA, Army.	do	MESA	EPA, Army	Army, FDA, DNA-AFRII.	FDA.

Key:

1. Human health effects research.
2. Ecological effects (plant, animal).
3. Criteria/standards development.
4. State/Federal liaison.
5. Licensing, certification, inspection.
6. Monitoring/surveillance.
7. Medical, diagnostic, therapeutic.
8. Collection/analysis of health data.
9. Collection/analysis of environmental data.
10. Miscellaneous biological/physical effects.
11. Other studies.

Abbreviations:

AF—Air Force.
ARPA—Advanced Research Projects Agency, DOD.
DNA-AFRII—Defense Nuclear Agency-Armed Forces Radiological Research Institute.
EPA—Environmental Protection Agency.
FAA—Federal Aviation Administration, DOT.
FDA—Food and Drug Administration (Bureau of Radiological Health).
FCC—Federal Communications Commission.
MESA—Mine Enforcement and Safety Administration.
NBS—National Bureau of Standards.
NIH—National Institutes of Health.
NIOSH—National Institute for Occupational Safety and Health.
OSHA—Occupational Safety and Health Administration.
OTP—Office of Telecommunications Policy.
VA—Veterans' Administration.

GENERAL OVERLAP OF FEDERAL RESEARCH, REGULATORY, AND DEVELOPMENT—PROGRAMS CONCERNED WITH IONIZING RADIATION

Year	1	2	3	4	5	6	7	8	9	10	11	12	13
1968	FAA, NIOSH, AF, Navy, AEC, DNA–AFRII.	NIH, AEC.	USDA	NBS, AF, MTB.	AF, MTB	Army	FAA, NBS, AF, NIH, USDA, Army.	NBS, NIH, AEC, Army.	DNA–AFRII, Army.	AF, Army	DNA–AFRII, NBS, AEC, Army.	NBS, NIH, AEC, Army, DNA–AFRII.	
1969	FAA, NIOSH, AF, Navy, NIH, AEC, FDA, DNA–AFRII.	NIH, AEC.		NBS, MESA, AF, MTB, FDA.	MESA, AF, MTB.	MESA, FDA, Army.	NBS, AF, NIH, USDA, Army.	do	MESA, Army, DNA–AFRII.	MESA, AF, Army.	DNA–AFRII, NBS, AEC, FDA, Army.	MESA, NBS, NIH, AEC, FDA, Army, DNA–AFRII.	
1970	FAA, NIOSH, Navy, AF, NIH, AEC, FDA, DNA–AFRII.	AEC		NBS, MESA, AF, MTB, FDA, Army.	MESA, AF, MTB, FDA.	do	NBS, AF, NIH, USDA, FDA, Army.	do	do	do	NBS, AEC, FDA, Army, DNA–AFRII.	NBS, MESA, NIH, AEC, FDA, DNA, Army.	
1971	FAA, NIOSH, AF, NIH, AEC, FDA, DNA–AFRII.	AEC		OSHA, NBS, MESA, AF, MTB, FDA, Army.	NIOSH, MESA, AF, MTB, FDA.	do	do	do	do	do	do	NBS, MESA, NIH, AEC, FDA, Army, DNA–AFRII.	
1972	FAA, NIOSH, AF, NIH, AEC, EPA, FDA, DNA–AFRII.	AEC	USDA	OSHA, NBS, AF, MESA, MTB, FDA, Army.	NIOSH, MESA, AF, MTB, FDA.	do	NIOSH, Navy, NBS, AF, NIH, USDA, FDA, Army.	do	do	do	do	NBS, MESA, NIH, AEC, FDA, DNA–AFRII.	
1973	do	AEC		do	NIOSH, MESA, AF, MTB, EPA, FDA.	do	do	NBS, NIH, AEC, EPA, Army.	MESA, EPA, Army, DNA–AFRII.	MESA, EPA, AF, Army.	do	NBS, MESA, NIH, AEC, EPA, FDA, DNA–AFRII.	
1974	FAA, AF, NIH, AEC, EPA, FDA, NASA, DNA–AFRII.	AEC		OSHA, NBS, MESA, AF, MTB, FDA, Army.	NIOSH, OSHA, MESA, AF, MTB, EPA, FDA.	OSHA, MESA, FDA, Army	NIOSH, OSHA, AF, Navy, NBS, NIH, USDA, Army.	do	MESA, EPA, Army, INA, –AFRII.	do	NBS, AEC, NASA, Army, DNA–AFRII.	NBS, MESA, NIH, AEC, EPA, FDA, DNA–AFRII	

1975	FAA, NIOSH, AF, NIH, AEC, EPA, NASA, ERDA, DNA-AFRII.	ERDA		OSHA, NBS, MESA, AF, MTB, NRC, Army.	NIOSH, OSHA, NBS, MESA, AF, MTB, NRC, EPA, FDA.	OSHA, MESA, NRC, FDA, Army.	NIOSH, OSHA, Navy, NBS, AF, NIH, NRC, USDA, FDA, Army.	NBS, NIH, NRC, AEC, EPA, Army.	do	do	NBS, AEC, FDA, NASA Army, DNA-AFRII.	NBS, MESA, NIH, AEC, EPA, FDA, DNA-AFRII	NRC
1976	FAA, NIOSH, AF, NIH, NRC, ERDA, EPA FDA, NASA, DNA-AFRII.	NRC, ERDA.	NRC, USDA.	OSHA, NBS, AF, MESA, MTB, NRC, ERDA, EPA, FDA, Army.	NIOSH, OSHA, NBS, MESA, AF, MTB, NRC, EPA, FDA.	do	NIOSH, OSHA, Navy, NBS, AF, NIH, NRC, ERDA, USDA, Army.	NBS, NIH, NRC, ERDA, EPA Army.	MESA, NRC, EPA, Army DNA-AFRII.	MESA, AF, NRC, EPA, Army.	NBS, ERDA, FDA, NASA, DNA-AFRII.	NBS, MESA, NIH, ERDA, EPA, FDA, DNA-AFRII.	NRC
1977	do	NRC, ERDA.	NRC, USDA.	do	NIOSH, OSHA, NBS, MESA, AF, MTB, NRC, EPA, FDA.	do	NIOSH, OSHA, Navy, NBS, AF, NIH, NRC, ERDA, FDA, Army.	NBS, NIH, NRC, ERDA, EPA Army.	MESA, NRC, Army, DNA-AFRII.	do	NBS, ERDA, FDA, NASA DNA-AFRII.	NBS, MESA, NIH, ERDA, EPA, FDA, DNA-AFRII.	NRC
1978	FAA, NIOSH, AF, NIH, NRC, ERDA, FDA, NASA, DNA-AFRII.	NRC, ERDA	NRC, USDA.	OSHA, NBS, MESA, AF, MTB, NRC, ERDA, EPA, FDA, Army.	NIOSH, OSHA, NBS, MESA, AF, MTB, NRC, EPA, FDA.	do	Navy, NBS, AF, NIH, NRC, ERDA, USDA, FDA, Army.	NBS, NIH, ERDA, EPA, Army.	do	do	NBS, ERDA, FDA, NASA, INA-AFRII	NBS, MESA, NIH, ERDA, EPA, FDA, DNA-AFRII	NRC

Key:

1. Human health effects research.
2. Ecological effects (plant, animal).
3. Agricultural effects (plant, animal).
4. Criteria/standards development.
5. State/Federal liaison.
6. Licensing, certification, inspection.
7. Monitoring/surveillance.
8. Medical, diagnostic, therapeutic.
9. Collection/analysis of health data.
10. Collection/analysis of environmental data.
11. Miscellaneous bioligical/physical effects.
12. Other studies.
13. Reactor safety environmental surveys.

Abbreviations:

AEC—Atomic Energy Commission.
AF—Air Force.
ARPA—Advanced Research Projects Agency, DOD.
DNA-AFRII—Defense Nuclear Agency-Armed Forces Radiological Research Institute.
EPA—Environmental Protection Agency.
ERDA—Energy Research and Development Agency
FAA—Federal Aviation Administration.
MESA—Mine Enforcement and Safety Administration.
MTB—Materials Transportation Bureau.
NBS—National Bureau of Standards.
NIH—National Institutes of Health.
NIOSH—National Institute for Occupational Safety and Health.
NRC—Nuclear Regulatory Commission.
OSHA—Occupational Safety and Health Administration.
USDA—U.S. Department of Agriculture.

The responses received from the Federal agencies follow:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., June 8, 1977.

Hon. WENDELL H. FORD,
Chairman, Subcommittee on Consumer, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR SENATOR FORD: This is in reply to your letter of May 19, 1977, in which you request information on our radiation health program for use in your Subcommittee's upcoming hearings on Federal radiation health research and regulation.

Enclosed are answers to the four specific questions contained in your letter. These questions concern radiation and our administration of the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602). In addition, we have enclosed project funding allocation information for radiation programs which cover 1973 to present.

As discussed with the Subcommittee staff, we have not finished the matrices on ionizing and nonionizing radiation. These will be forwarded to you within the next few days.

Sincerely yours,

DONALD KENNEDY,
Commissioner of Food and Drugs.

Enclosures.

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. The regulatory authority of the Food and Drug Administration's Bureau of Radiological Health began with passage of the Radiation Control for Health and Safety Act of 1968, when the Bureau was a unit of the no longer extant Environmental Control Administration. The President's Reorganization Plan No. 3 of 1970 established the Environmental Protection Agency and transferred out of the Bureau of Radiological Health into EPA (which was created by the plan) all of the former's environmental radiation functions. The BRH functions specifically cited by Plan No. 3 as remaining with BRH included such responsibilities as "regulation of radiation from consumer products"; "radiation as used in the healing arts"; and "research, technical assistance, and training" as they related to the Bureau's basic functions.

The Reorganization Plan No. 3 also cited "occupational exposures to radiation" as a function to remain with the Bureau. Over the years, the Bureau has cooperated with the National Institute of Occupational Safety and Health and the Labor Department's Occupational Safety and Health Administration, the two agencies at the Federal level which have lead responsibilities in the area of occupational health.

The overall effect of the foregoing changes was to place greater emphasis upon the Bureau's responsibility for setting and enforcing equipment performance standards for certain consumer goods, for equipment used in the healing arts, equipment used in commercial and industrial settings (including airport baggage inspection units), and the development of a strong, non-regulatory capacity in the field of use and user controls, equipment user training programs (especially for operators of diagnostic X-ray equipment), and the publication of operator instructions, guidelines, and recommendations concerning correct methods of application of diagnostic radiation (X-radiation during pregnancy, gonad shielding, X-ray use for screening purposes). In other words, the changes that have taken place in the Bureau's program orientation have served to sharpen rather than lessen specific Bureau concerns for protecting the public health from equipment-produced radiation.

At the same time, despite the fact that the Bureau does not have regulatory authority for the control and use of naturally occurring and accelerator-produced radioactive materials, the Bureau has maintained a relatively small but effective program in this area. This has been done under the Bureau mandate to reduce unnecessary or unproductive exposure to all radiation. In this connection, the Bureau has maintained a strong support capacity in the field of nuclear medicine and radiopharmaceuticals.

Incorporation into the FDA has had only positive effects upon the Bureau's overall efforts in standards-setting, guideline development, surveillance and monitoring, and oversight and auditing of manufacturers' corrective action programs to bring products into compliance with an applicable standard, and/or to correct a defect (applicable to electronic products manufactured on or after October 1968, date of passage of the Radiation Control for Health and Safety Act of 1968, but prior to promulgation of an applicable performance standard.)

Question 2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

Answer. Throughout almost all the operating history of the Food and Drug Administration's Bureau of Radiological Health, the Bureau has developed and maintained a close working relationship with State radiological health programs. During the years 1959 through 1977, the Bureau and/or its predecessor agency provided State radiation programs with manpower support through the assignment of personnel. (This included State assignees [full-time professional radiological health personnel] and Commissioned Officer Student Training and Extern Programs.) Through 1977, there will have been 248 assignees (including one scheduled in 1977) and 141 students. During the years 1963 through 1967, the Bureau provided "formula" grants to States in support of their radiological health programs. Total funds involved in the five years amounted to $9,649,200.

In a number of situations, these State assignees returned to the Bureau, bringing back an understanding of State radiation control program problems which helped the Bureau further improve its relations with the States. One principal result was continued support and involvement of the State programs in the Bureau's development of an effective nationwide radiation protection program at all levels.

Section 360(e) of the Radiation Control Act provides that the Bureau may accept enforcement support from State radiation program agencies. As an example of how this authority has been implemented, the Bureau developed contracts with States in FY 75 to assist in the enforcement of the Federal performance standard for diagnostic X-ray equipment. These contracts call for the inspection of certified X-ray systems and providing to the Bureau compliance data based on the inspection of newly certified diagnostic X-ray systems to assure that the requirements of the performance standard are being met. States that participate under these contracts also supplement the amount of information obtained by field components of FDA. Currently, in FY 77, there are contracts with 18 States, with a funding level of approximately $310,000.

Under provisions of the Radiation Control for Health and Safety Act, the Bureau is to "maintain liaison with and receive information from other Federal and State departments and agencies with related interests . . . etc. . . ." (Sec. 356(a)(3)). Largely, however, continuing program activities developed by the Bureau are carried out in conjunction with State radiation protection agencies on a voluntary basis.

The Nationwide Evaluation of X-Ray Trends, known by the acronym NEXT, is an example of a Bureau cooperative effort with the States. It is designed to collect data on exposure and other parameters associated with radiographic procedures through on-site surveys of X-ray installations.

Additionally, programs such as BENT (Breast Exposure: Nationwide Trends), a quality assurance effort to improve techniques employed during mammography, and DENT (Dental Exposure Normalization Technique), an older and conceptually parallel program, further illustrate activities currently conducted jointly by the BRH and State radiation protection agencies. DENT is presently used by 36 Federal, State, and local radiation control agencies, involving an estimated two-thirds of the dental machines in the U.S. Both BENT and DENT utilize efficient methodologies to locate high and low exposure facilities and link an educational aspect to help effect reductions in unnecessary patient exposure.

NEXT, in 1976, involved 43 State or local radiological health programs as well as seven Federal agencies. BENT currently has provided operational training to staff of 13 State agencies and will add at least another four by the end of FY 77. This is in addition to an original five pilot State programs. The National Cancer Institute has provided support to BENT through a $300.000 grant over the next two years. This will enable participation of additional State agencies in the program. In an effort to broaden the conceptual quality assurance ideas embodied in DENT and BENT, the Bureau is presently working with a task force of State representatives to develop a methodology for an action program designed to improve diagnostic image quality and reduce patient exposture. The methodology, originally pilot-tested in West Virginia, will include a testing aspect to identify problem areas and an educational aspect to help facilities institute quality assurance programs on their own. The DENT program is, or has been, active in 37 States.

The Conference of Radiation Control Program Directors, which consists of heads of all State and municipal radiation control programs, as well as from D.C., Puerto Rico, the Virgin Islands, is a corporate body which came into existence about ten years ago with the active support of the Bureau. Annual national meetings of the Conference are jointly supported by the Conference, itself, by the FDA, NRC, and EPA.

To a lesser degree, but wherever the opportunity presents itself, the Bureau either has contracts with or agreements for expanding and developing surveillance methodologies, compliance instrumentation research, standards and guidelines development with such Federal agencies as the National Bureau of Standards (equipment development) and the National Institute of Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), the Consumer Product Safety Commission, to name a few examples.

Additional evidence indicative of Bureau-State activity in radiation protection is the relationship demonstrated in the joint development of model State regulations. These regulations are based upon counterpart Federal regulations and standards, and designed to fit the needs of the States for incorporating in whole or part into respective State regulations. Over 40 States have developed comprehensive radiation control regulations based on the use of this model.

There is no basic confusion on the Bureau's part concerning the respective responsibilities of State and Federal agencies, speaking with respect to all State agencies and most Federal agencies. The exception to this is FDA's relationship with EPA in the field of radiation protection. The FDA's position is based upon a number of factors: in particular, the President's Reorganization Plan No. 3 of 1970 in which it is stated that "radiation as used in the healing arts" is a function to be carried out by the Bureau of Radiological Health. In its interpretation of the responsibilities of the now defunct Federal Radiation Council, the EPA has claimed a role at the Federal level for the development of guidelines and standards for "radiation as used in the healing arts." Commissioner Kennedy and EPA Administrator Douglas Costle have begun discussions to resolve this and other matters requiring close coordination and cooperation between the two agencies.

The Federal-State relationship with respect to the Federal radiation control programs is defined in the Radiation Control for Health and Safety Act (Section 360(f)), "Effect on State Standards." No State is permitted to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. The question of whether the Food and Drug Administration's radiological health programs could be improved, whether there are deficiencies in operational elements of the FDA radiological health protection programs, and whether present funding levels are adequate—these questions/issues may properly be considered a function of how extensive and in-depth a radiological health program is desired, or is desirable.

A General Accounting Office report, "Radiation Exposure from Diagnostic X-Rays Could Be Reduced," of November 24, 1976, spoke to only one aspect of the Bureau's total radiation-related responsibilities (ionizing radiation). But, in doing so the report, in its second of three recommendations, recommended the allocation to the Bureau of "additional resources" to expedite the review of manufacturers' diagnostic X-ray equipment reports and the inspection of manufacturers."

The report gave no indication of the magnitude of the amount of "additional resources" that it believed would be required.

A Bureau inquiry into the problems associated with the compliance of diagnostic X-ray equipment elicited the information that there is a considerable shortfall in the state of compliance of newly installed diagnostic X-ray equipment.

The average for all manufacturers is about 30 percent, with one manufacturer's equipment showing a 50 percent failure rate with respect to the standard.

A National X-Ray Control System, a Bureau designed proposal to effect a greater degree of conformance to the diagnostic X-ray equipment standard, could cost approximately $70 million over a five-year period.

The National X-Ray Control System (NXCS) is dedicated to dramatically reducing the $2 billion spent each year by the American public for X-rays that have a low probability of affecting patient management. Similarly, ill health resulting from the exposure of these unneeded X-rays, as well as unnecessary exposure due to poor techniques and faulty equipment, is a primary thrust of NXCS. The health care costs resulting from that unnecessary exposure preventable with current technology, exceeds $500 million per year.

The Bureau currently has approximately 18 State radiological health programs under contract (costing approximately $310,000 per year) in order to assure the compliance of newly-installed diagnostic X-ray systems with the diagnostic X-ray equipment performance standard. It is estimated that. in order to do a more effective job of determining compliance with the standard, the Bureau needs the support of the States at a cost of $900,000 per year. It is estimated that $4 million would support an inspection program for all new installations, each of which has the potential for unnecessarily exposing patients.

With respect to whether there are any present deficiencies in the FDA's radiation control program, again it is less a question of deficiency than it is a matter of deciding what other areas related to radiation health and safety one wishes to control. For example, whereby the Radiation Control for Health and Safety Act requires the FDA to conduct and administer an electronic product radiation control program, it only provides authority to mandate and require adherence to equipment performance standards. The manner of use of the equipment, the issues of educational and credentialing requirements for medical radiation technologists (e.g., X-ray technologists), and who should stipulate such requirements (by the States or the Federal government), the effectiveness and safeness of radiation-emitting devices—none of these aspects of health protection is mandated by the Act. The charge to develop user and use guidelines and/or recommendations and the authority to decide about the safeness and effectiveness of equipment, are implied but not provided with regulatory backing by the Act. With respect to guidelines for user training and credentialing, the GAO report mentioned previously recommended establishment of a uniform national credentialing system for medical X-ray personnel.

The guidelines, recommendations, training programs, and State coordinated surveillance and monitoring systems that the FDA has developed and promoted have resulted from the Bureau's moral commitment to reducing unnecessary patient exposure.

Beyond such compliance-related functions lie very important research areas: equipment, instrumentation, and measurements; biologic effects and epidemiology. There are specific modalities such as ultrasound, that would appear to require much more research-developed data than is presently available in the face of the need of the FDA to know more than is currently available about ultrasound. The effects of long-term, low levels of microwave radiation is another area of concern.

Funding for additional research is always an issue with two sides, one that can, perhaps, more appropriately be resolved by an interested and informed third party.

Question 4. What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

Answer. The question of consolidating all Federal radiation activities into one agency hinges, in part, on the answer to "How much is too much?" It is possible that such a consolidation proposal would produce a monolithic structure that would be unwieldy, and too cumbersome to react with alacrity to public health and consumer needs, as well as to industry and commercial radiation needs.

Beyond the question of response time lies the issue of response capability. Those with expertise in nuclear matters are not, per se, possessed of expertness in non-ionizing radiation equipment operation. This suggests there may be little if any manpower savings in establishing one overall radiation control Agency. This brings us to what we feel is probably the most important observation to be made about the viableness of a single radiation control agency at the Federal level:

the creation of such an agency would move a significant element of the Federal radiation control effort out of the Federal agency responsible for the health of the population. The regulation of the use of radiation in healing arts, where complex individual and professional judgments are made, requires an agency which can respond specifically to these considerations and which is not encumbered by concerns in other areas.

Use of radiation in the healing arts is somewhat unique in that, of all radiation activities, it is the one which requires the exposure of humans, whether in diagnosis or therapy. Although other Federal radiation control agencies recognize the cost/benefit equation in estimating the degree of permissible radiation exposure, such a balancing of pros and cons is an essential element in the use of radiation in the healing arts.

The consolidation of Federal agencies that are concerned with different applications of radiation within one structure could produce more heat than light, more controversy than solution. Under the circumstances, and in light of the sometimes conflicting justifications in the use of radioactive materials and production of radiation producing equipment (consumer, commercial, medical), one finds no particularly compelling reason for or combining all present Federal agencies that deal with various radiation activities into one unit.

FOOD AND DRUG ADMINISTRATION

RESOURCES FOR RADIOLOGICAL HEALTH PROGRAMS

[Funding allocation in thousands of dollars]

	Fiscal year 1977 estimate	197TQ	Fiscal year 1976	Fiscal year 1975	Fiscal year 1974	Fiscal year 1973
Ionizing radiation products and devices	5,967	2,060	6,815	6,081	5,955	5,35
Ionizing radiation use control	5,416	1,308	4,999	4,461	3,818	2,881
RF-microwave radiation	2,231	472	2,578	3,040	2,779	2,528
Light and sonic radiation	5,503	824	3,696	3,423	2,940	1,817
Total	19,117	4,664	18,088	17,005	15,492	12,576

BUDGETED POSITIONS FOR RADIOLOGICAL HEALTH PROGRAMS

	Fiscal year—				
	1977 (estimate)	1976	1975	1974	1973
Ionizing radiation products and devices	181	187	183	173	170
Ionizing radiation use control	130	130	117	101	102
RF-microwave radiation	57	67	76	84	100
Light and sonic radiation	106	82	80	78	64
Total	474	466	456	436	436

Note: A combination of organization and program management system changes in the years prior to fiscal year 1973 prevents our obtaining and presenting comparable financial data for the Bureau. A sequence of changes started in December 1968 (fiscal year 1969) when the National Center for Radiological Health became the Bureau of Radiological Health as a component of the Environmental Control Administration, Consumer Protection and Environmental Health Service. Just 2 yr (fiscal year 1971) later the Bureau was assigned to the Environmental Health Service when it became the successor to the Consumer Protection and Environmental Health Service. 1 yr later (fiscal year 1972) pursuant to Presidential Reorganization Plan No. 3 of 1970 the Bureau was split with components going to EPA and FDA. To further complicate the compilation of comparable data the PMS (program management system) was not established until fiscal year 1973.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Rockville, Md., June 15, 1977.

Hon. WENDELL H. FORD,
Chairman, Subcommittee on Consumer, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR SENATOR FORD: This is in further reply to your May 19 letter in which you requested information concerning radiation health programs to be used in your Committee's upcoming hearing on Federal radiation health research and regulation.

We are submitting the enclosed document which highlights the Agency's major efforts in the radiological health areas. These are the completed matrices that were enclosed in your May 19 letter. We have provided you earlier with the answers to the four questions contained in that letter.

It should be noted that the format of the matrices has been changed with the permission of your staff. We are enclosing the altered form to clarify for you the correlation between the "matrix column reference" number which appears in the document and the columns in the original matrix.

In addition, funding allocation information has been supplied to you earlier with the answers to your May 19 letter.

If you have any questions please contact me or Mr. Banks of my staff at 443-3793.

Sincerely yours,

ROBERT C. WETHERELL, Jr.,
Director, Office of Legislative Services.

Enclosures.

A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1978

Activity	Program Area (see legend below)	Matrix Column Reference
1. Issuance of proposed amendments to the diagnostic x-ray equipment performance standard for computed tomography (CT) systems.	II-C	2
2. Continuation of enforcement programs for TV receivers, cold-cathode gas discharge tubes, cabinet x-ray and diagnostic x-ray systems.	II-C	3
3. Contract with twenty States for inspection of diagnostic x-ray systems.	II-C	3
4. Issue mercury vapor lamp standard as a final rule.	III-C	2
5. Issue sunlamp standard as a final rule.	III-C	2
6. Continuation of enforcement program for laser products.	III-C	3
7. Propose amendments to the laser performance standard.	III-C	2
8. Develop enforcement programs for sunlamps and mercury vapor lamps.	III-C	3
9. Develop enforcement program for ultrasound therapy products.	III-C	3
10. Issue microwave diathermy standard as a proposed rule.	IV-C	2
11. Continuation of enforcement program for microwave ovens.	IV-C	3

Activity	Program Area (see legend below)	Matrix Column Reference
12. Continue developmental work on policy statement on utilization of intensifying screens.	II-B	6
13. Evaluate feasibility of general patient exposure limits using in-house organ dose analysis scheme.	II-B	6
14. Develop measurement protocols, test instrumentation and test methods for dose and image performance of computed tomography (CT) systems.	II-B	6
15. Intensify study of diagnostic information per unit dose and alternate concept standard.	II-B	6
16. Complete work on mammographic technique/exposure survey.	II-B	6
17. Initiate a laboratory clinical study to evaluate the relationship between physical parameters and diagnostic mammography and image receptor systems.	II-B	6
18. Design and conduct a pilot program to assess the procedures to be used in a nationwide program to survey medical accelerator exposures/doses in radiation therapy.	II-B	6
19. Design and conduct a technical survey of CRT and CRT devices to clarify and document x-ray exposures associated with such devices.	II-B	6
20. Expand in-house field measurement capability in the UV-Visible-IR region through a variety of instrument procurements, traceability programs for measurement standards, and instrument inter-comparisons.	III-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
21. Continue evaluation of consumer and medical noncoherent sources by extension of the present light sources measurement contract and associated product evaluation activities.	III-B	6
22. Investigate the feasibility of a light measurement assurance program.	III-B	6
23. Intensify evaluations of the performance of diagnostic ultrasonic devices from the standpoint of acoustic output and imaging characteristics.	III-B	6
24. Relate acoustic exposure levels and imaging performance of diagnostic ultrasound devices to risk/benefit analyses of this modality.	III-B	6
25. Design quality assurance test devices and procedures for the masurement and evaluation of acoustic output and imaging capability.	III-B	6
26. Develop compliance test methods and field instrumentation for microwave diathermy.	IV-B	6
27. Develop a collaborative effort with NCI on microwave cancer therapy.	IV-B	6
28. Conduct a clinical survey of microwave levels in hyperthemia treatment.	IV-B	6
29. Develop safety procedures for microwave cancer therapy operating personnel and patients.	IV-B	6
30. Develop plan to reduce exposure to RF sealers.	IV-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
31. Develop voluntary recommendations on the subjects of dental post-operative x rays, dental quality assurance procedures, and guidelines on patient exposure from specific x-ray examinations.	I-D	6
32. Produce audiovisual packages to teach consumer groups about protection against products which emit ratiation.	I-D	6
33. Complete part six of the multi-media packaged training series for x-ray technologists, covering quality assurance x-ray film processor procedures.	I-D	6
34. Administer on a nationwide basis a self-assessment test for x-ray technologists to aid in their continuing education.	I-D	6
35. Conduct a national survey to determine the environmental factors which affect the performance of x-ray machine operators.	I-B	6
36. Conduct a nationwide FDA/State program to identify those x-ray facilities delivering excessive patient exposure during mammography and to perform corrective consultation.	I-F	6
37. Develop performance parameters for scintillation cameras.	I-F	6
38. Develop quality control procedures for rectilinear scanners, dose calibrators, and radiopharmaceutical preparation.	I-D	6
39. Continuation of the nuclear medicine information system.	I-D	6
40. Initiation of a survey of medical accelerator units.	I-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
41. Develop guidelines and recommendations on quality control procedures for tele-therapy and accelerator-therapy units.	I-B	6
42. Continuation of disposal services for radium sources.	I-F	6
43. Continuation of the assessment of effects of low-level ionizing radiation exposure.	II-A	1
44. Continuation of the assessment of in-utero exposure to ionizing radiation.	II-A	1
45. Continuation of the assessment of the delayed effects of I^{131}.	II-A	1
46. Continuation of the assessment of the effects of low energy x rays.	II-A	1
47. Continuation of the assessment of the effects of light exposure.	III-A	1
48. Continuation of the assessment of vision and visual function.	III-A	1
49. Identification and assessment of the effects of ultrasound.	III-A	1
50. Assessment of heating in dental ultrasound.	III-A	1
51. Continuation of the study of effects of low levels of microwave radiation including repetitive pulses and chronic exposures.	IV-A	1
52. Identification and study of microwave induced diseases.	IV-A	1

LEGEND

(see next page)

LEGEND

I - Ionizing Radiation - Use Control
II - Ionizing Radiation - Products and Devices
III - Light & Sonic Radiation
IV - RF Microwave

A - Biological Effects Research
B - General Research
C - Performance Standards, Compliance and Surveillance
D - Education/Training
E - Federal/State Relations
F - Other

A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1977

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of a Notice of Intent to propose rules for ionizing radiation therapy equipment.	II-C	2
2. Continuation of enforcement programs for TV receivers, cold cathode gas discharge tubes, and diagnostic x-ray equipment systems.	II-C	3
3. Contracted with eighteen States for inspections of diagnostic x-ray systems.	II-C	3
4. Preparation of a final rule for an ultrasound therapy performance standard.	III-C	2
5. Preparation of a proposed performance standard for mercury vapor lamps.	III-C	2
6. Preparation of a proposed performance standard for sunlamps.	III-C	2
7. Continuation of laser products enforcement program.	III-C	3
8. Developmental work toward performance standard for microwave diathermy equipment.	IV-C	2
9. Continuation of microwave oven enforcement program.	IV-C	3
10. Development of a radiation impact rating index for medical x-ray procedures based on appropriate weighting of all important organ doses.	II-B	6
11. Development of an appropriate application and evaluation procedure for use in association with the NEXT system.	II-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
12. Provide organ dose estimates for Agency environmental assessment reports.	II-B	6
13. Development of handbooks on organ doses for various medical x-ray and fluoroscopic examinations.	II-D	6
14. Application of accumulated organ dose data to various national and international organization dose estimation projects.	II-B	6
15. Publication of accurate measurements of x-ray primary beam exposure rates typical of diagnostic x-ray equipment.	II-B	6
16. Continuation of the development and evaluation of instrumentation and procedures for effective enforcement of all ionizing radiation defect and compliance actions.	II-B	6
17. Quantitation of patient dose data resulting from CT scanner examinations as a function of image content.	II-B	6
18. Development of methods to minimize the radiation exposure associated with mammography while retaining desired diagnostic information.	II-B	6
19. Continuation of the development of methods and devices to be used in evaluating the performance characteristics of diagnostic x-ray systems and related equipment.	II-B	6
20. Continuation and expansion of calibration facilities to support compliance and non-regulatory activities.	II-B	6
21. Evaluation of image receptor performance and the relationship between image quality and exposure.	II-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
22. Continuation of the development of instruments, calibration standards, and methods to support biological research, compliance programs, and light hazards analysis for UV, visible, and infrared radiation sources.	III-B	6
23. Establishment of a standards calibration facility and protocols and techniques to support bioeffects research and compliance programs for ultrasonic sources.	III-B	6
24. Evaluation of medical diagnostic ultrasonic equipment to develop documentation for the parameters which should be specified in an ultrasonic diagnostic equipment performance standard.	III-B	6
25. Implementation of product investigations for sources of noncoherent radiation.	II-B	6
26. Development of reliable field measurement capabilities, including techniques, instrumentation, and the calibration for both research and routine application needs for RF and microwave sources.	IV-B	6
27. Establishment of test methodologies and selection of instruments to provide compliance testing capabilities for microwave diathermy.	IV-B	6
28. Development of new diathermy applicators which will meet proposed leakage requirements of the diathermy standard while providing satisfactory clinical performance.	IV-B	6
29. Evaluation of citizens band radio to establish acute hazards associated with the use of hand-held and mobile units.	IV-B	6
30. Preparation of a technical overview on medical x rays during pregnancy.	I-D	6

Activity	Program Area (see legend below)	Matrix Column Reference
31. Implementation of a consumer education program in the medical and consumer radiation program.	I-D	6
32. Completion of a study on the effectiveness of selective criteria for ordering of skull x rays following trauma.	I-D	6
33. Marketed parts four and five of the packaged training series for x-ray technologists.	I-D	6
34. Initiation of the development of voluntary medical radiation recommendations concerning x rays during pregnancy and quality assurance programs for diagnostic medical x-ray facilities.	I-D	6
35. Publication of a catalog of available x-ray quality assurance tools and techniques.	I-D	6
36. Continuation and expansion of quality assurance (BENT) program for mammography facilities.	I-D	6
37. Development of a whole body scanner for determination of biological distribution of radiopharmaceuticals in patients.	II-B	6
38. Implementation of guidelines for the quality assurance testing of scintillation cameras used in nuclear medicine.	II-D	6
39. Development of uniform criteria for the evaluation of products containing naturally-occurring or accelerator-produced radioactive materials via a Federal/State task force.	II-E	6
40. Evaluation of Co^{60} teletherapy units in cancer treatment facilities to determine accuracy and precision with which a specified dose of radiation is delivered.	II-B	6
41. Consumer product radiation symposium conducted.	II-D	6
42. Preparation of a mathematical model to assess risks and benefits of mammography.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
43. Refine and test biophysical dosimetry model in study of radiation-induced developmental anomalies.	II-A	1
44. Continuation of the study on effects of ionizing radiation on selected processes of development.	II-A	1
45. Investigate dose responses of thyroid from I^{131} and localized thyroid and pituitary x-irradiation in rats.	II-A	1
46. Study of cytogenic and teratogenic effects following x-ray exposure.	II-A	1
47. Analyze somatic chromosome aberration of x-rayed embryonic cells.	II-A	1
48. Study of breast cancer and other malignancies following multiple fluoroscopies.	II-A	1
49. Study of diagnostic I^{131} exposure in children.	II-A	1
50. Study of thyroid tumor risk from scalp x-irradiation during childhood.	II-A	1
51. Continuation of a followup study of persons treated for thyrotoxicosis.	II-A	1
52. Conduct of an analysis of the critical issues of diagnostic ultrasound.	III-A	1
53. Followup study of children exposed in-utero to ultrasound.	III-A	1
54. Study of visual function and pathology from light stress.	III-A	1
55. Study of light-induced mutagenesis.	III-A	1
56. Study of enhancement of viral infections by light.	III-A	1
57. Study of hyperbilirubinemia and visual damage following light exposure.	III-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
58. Development of UV exposure recommendation.	III-A	1
59. Update review of risks and benefits of photodynamic therapy for herpes simplex infections.	III-A	1
60. Continuation of the study on effects of occupational exposure to radar.	IV-A	1
61. Continuation of the study on effects on offspring of men exposed to radar.	IV-A	1

LEGEND

I - Ionizing Radiation - Use Control

II - Ionizing Radiation - Products and Devices

III - Light & Sonic Radiation

IV - RF Microwaves

A - Biological Effects Research

B - General Research

C - Performance Standards, Compliance and Surveillance

D - Education/Training

E - Federal/State Relations

F - Other

A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1976

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of Notice of Intent to propose rules for computed tomograph (CT) systems.	II-C	2
2. Continuation of cabinet x-ray, diagnostic x-ray systems, TV receiver, and cold-cathode gas discharge tube enforcement programs.	II-C	3
3. Contracted with eighteen States for inspection of diagnostic x-ray systems.	II-C	3
4. Publication of proposed ultrasound therapy standard.	III-C	2
5. Publication of proposed criteria for mercury vapor lamps.	III-C	2
6. Developmental work for sunlamp performance standard.	III-C	2
7. Initiation of an enforcement program for laser performance standard.	III-C	3
8. Developmental work for microwave diathermy equipment.	IV-C	2
9. Continuation of microwave oven enforcement program.	IV-C	3
10. Development of a system for estimating organ doses as a function of the physical parameters used during radiology procedures.	II-B	6
11. Installation of an automated system for calibrating and maintaining records of x-ray survey instruments.	II-F	6

Activity	Program Area (see legend below)	Matrix Column Reference
12. Establishment of a "guide number" for determining and providing illumination levels for various light sources without exceeding a specified UV exposure limit.	III-B	6
13. Transfer power meter made available to laser manufacturers.	III-F	6
14. Contracted to characterize and measure radiation emission levels from various illumination sources.	III-B	6
15. Survey initiated to evaluate the performance and use of diagnostic ultrasound equipment in 50 U.S. facilities.	III-B	6
16. Development of portable ultrasound measurement device under contract.	III-B	6
17. Development of a computer program based on a mathematical theory which predicts absorbed power density (of microwave radiation) at any point inside an exposed body.	IV-B	6
18. Development of a miniature microwave field probe and optical telemetry system.	IV-B	6
19. Study of the range and magnitude of microwave radiation exposure associated with marine radar units.	IV-B	6
20. Establishment of a formal system using the FEDERAL REGISTER to issue voluntary medical radiation recommendations, defining and delineating good radiation protection practices.	II-D	6
21. Mailed gonad shielding literature to all U.S. radiologists.	II-D	6
22. Conducted a national conference on the quality assurance aspects of film and screen selection in diagnostic radiology.	II-D	6

Activity	Program Area (see legend below)	Matrix Column Reference
23. Production of a film on radiation protection in the field of industrial x ray which subsequently won a national award.	II-D	6
24. The Dental Exposure Normalization Technique was expanded to twenty-nine State agencies.	II-F	6
25. Performed a pilot study to determine the environmental factors which affect the performance of medical x-ray technologists.	II-B	6
26. Initiation of an FDA/State program to identify those x-ray facilities delivering excessive patient exposure during mammography and to perform corrective consultation.	II-F	6
27. Development of a series of training workshops on quality assurance in nuclear medicine for nuclear medicine technologists.	II-D	6
28. Establishment of an intramural task force on short-lived radionuclides for medical applications.	II-F	6
29. Conducted radiopharmaceutical dosimetry symposium.	II-D	6
30. Development of performance criteria for personnel monitoring.	II-F	6
31. Study of effects of ionizing radiation on fetal growth and biochemical development.	II-A	1
32. Study of biological processes correlated with delayed radiation diseases.	II-A	1
33. Continuation and expansion of Oxford survey of childhood cancers.	II-A	1
34. Study of thyroid tumor risk from scalp x-irradiation during childhood.	II-A	1
35. Creation of intramural task force for biological basis for x rays during pregnancy.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
36. Development of a biological basis for justification of gonad shielding recommendation.	II-A	1
37. Analyze data related to phototherapy - neurotoxicity of hyperbilirubinemia in newborn.	III-A	1
38. Study of enhancement of viral infections by light.	III-A	1
39. Study of visual function and pathology from light stress.	III-A	1
40. Study of light-induced mutagenesis.	III-A	1
41. Evaluation of material relevant to biological effects aspects of laser standard.	III-A	1
42. Development of biological basis for sunlamp standard.	III-A	1
43. Development of biological basis for Agency action with Nuva-Lite.	III-A	1
44. Investigate reported incidents involving mercury vapor lamps and UV dental apparatuses.	III-A	1
45. Continuation of study on occupational exposures to radar.	IV-A	1
46. Study of effects on offspring of men with high level exposure to microwave radiation.	IV-A	1
47. Review of microwave oven exemption.	IV-A	3

LEGEND

I - Ionizing Radiation - Use Control

II - Ionizing Radiation - Products and Devices

III - Light & Sonic Radiation

IV - RF Microwave

A - Biological Effects Research

B - General Research

C - Performance Standards, Compliance and Surveillance

D - Education/Training

E - Federal/State Relations

F - Other

A SUMMARY OF THE FOOD AND DRUG ADMINISTRATION'S RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1975

Activity	Program Area (see legend below)	Matrix Column Reference
1. Continuation of cabinet x-ray and diagnostic x-ray systems enforcement programs.	II-C	3
2. Contracted with eighteen States for inspection of certified diagnostic x-ray systems.	II-C	3
3. Continuation of TV receiver and cold-cathode gas discharge tube enforcement programs.	II-C	3
4. Continuation of x-ray equipment assemblers' workshops.	II-D	3
5. Publication of assemblers' guide to diagnostic x-ray systems.	II-D	3
6. Study of the use and design of medical linear accelerators.	II-B	6
7. Publication of final laser preformance standard.	III-C	2
8. Developmental work for ultrasound therapy standard.	III-C	2
9. Developmental work for mercury vapor lamp performance standard.	III-C	2
10. Developmental work for sunlamp performance standard.	III-C	2
11. Publication of Notice of Intent to regulate microwave diathermy equipment.	IV-C	2

Activity	Program Area (see legend below	Matrix Column Reference
12. Continuation of microwave oven enforcement program.	IV-C	3
13. Survey of electron microscopes for for x-ray leakage.	II-C	3
14. Development of light measuring device for diagnostic x-ray systems compliance testing.	II-B	6
15. Patent assigned to compliance test stand for diagnostic x-ray systems.	II-F	6
16. Development of a portable instrument for measuring radiation exposure and exposure time.	II-B	6
17. Final report issued on the nationwide X-Ray Exposure Studies.	II-B	6
18. Completion of physician Radiological Health Sciences Learning Laboratory.	I-D	6
19. Establishment of an accession system to physician Learning Laboratory.	I-D	6
20. Report on the performance of medical x-ray technologists and their contribution to unnecessary patient exposure completed.	I-B	6
21. Provided criteria pertaining to x-ray technologist qualifications to Medicare program.	I-F	3
22. Assistance to Civil Service Commission on x-ray technologist qualifications.	I-F	3
23. Pilot test of quality assurance tools and techniques.	I-D	6
24. Study of radionuclide pollution of the Ohio River. (Joint FDA/EPA Project)	I-B	6
25. Study of efficacy and radiation dose of several radionuclide myocardial imaging agents.	I-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
26. Design of a Computer Assisted Medical Internal Radiation Dosimetry (CAMIRD) system).	I-B	6
27. National conference on I^{123} applications in nuclear medicine.	I-D	6
28. Design of a second generation nuclear medicine reporting and data storage system (NUMEDACON).	I-B	6
29. Testing of laser eyewear.	III-B	6
30. Laser calorimeter system validated using the National Bureau of Standards system.	III-B	6
31. Completion of a system to visualize and measure output characteristics of ultrasound diagnostic devices.	III-B	6
32. Field survey of diagnostic ultrasound equipment.	III-B	6
33. Development of new mathematical techniques and computer programs for demonstrating distribution of RF and microwave energy.	IV-B	6
34. Survey of microwave diathermy units.	IV-B	6
35. Study of chronic radiation effects in dogs.	II-A	1
36. Study of biochemical development as a result of in-utero x-ray exposure.	II-A	1
37. Investigation of processes in x-ray initiation of delayed radiation disease.	II-A	1
38. Study of the promotion of RNA virus leukemia by ionizing radiation.	II-A	1
39. Development of a method to assess degree of somatic risk from partial and whole body irradiation with x-rays.	II-A	1
40. Continuation of Oxford survey of childhood cancers.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
41. Followup study of U.S. Army x-ray technologists to determine overall mortality rates.	II-A	1
42. Continuation of Radiation Registry for Physicians.	II-A	1
43. Study of exposure to I^{131} and development of thyroid neoplasms.	II-A	1
44. Development of guidelines for x-irradiation during pregnancy.	II-F	6
45. Development of guidelines for medical practitioners who use ionizing radiation in the treatment of disease.	II-F	6
46. Hospital surveys of phototherapy and obstetric ultrasound.	III-A	1
47. Study of visual function and pathology from light stress.	III-A	1
48. Study of enhancement of viral infections by light.	III-A	1
49. Study of infrared radiation-induced mutagenesis.	III-A	1
50. Study of ultrasonic effects in reproduction and fetal development.	III-A	1
51. Investigation of the biophysical characterization of ultrasound exposures.	III-A	1
52. Development of biomedical basis for ultrasound therapy standard.	III-A	1
53. Biophysical characterization of microwave exposures of biological specimens.	IV-A	1
54. Study of effect of chronic low-level microwave irradiation on growth, development, protein and energy metabolism in rats.	IV-A	1
55. Study of animal behavior and neurochemistry of the central nervous system after microwave radiation exposure.	IV-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
56. Study of mutagenic, chromosomal, and reproductive effects of microwaves.	IV-A	1
57. Development of a wavelength apparatus for the study of microwave cataractogenesis.	IV-A	1
58. Study of microwave radiation effects; occupational exposure to radar.	IV-A	1
59. Study of effects of offspring of high level military exposure to microwave radiation.	IV-A	1

LEGEND

I - Ionizing Radiation - Use Control

II - Ionizing Radiation - Products and Devices

III - Light & Sonic Radiation

IV - RF Microwave

A - Biological Effects Research

B - General Research

C - Performance Standards, Compliance and Surveillance

D - Education/Training

E - Federal/State Relations

F - Other

A SUMMARY OF THE FOOD AND DRUG ADMINISTRATION'S RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1974

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of final cabinet x-ray performance standard.	II-C	2
2. Initiation of enforcement program for diagnostic x-ray systems.	II-C	3
3. Initiation of enforcement program for cabinet x-ray systems.	II-C	3
4. Contracted with seven States for purposes of diagnostic x-ray equipment inspection.	II-C	3
5. Continuation of TV receiver and cold-cathode gas discharge tube enforcement programs.	II-C	3
6. Conducted nationwide workshops for assemblers of diagnostic x-ray systems.	II-D	3
7. Published assembler's guide (handbook) for practitioners.	II-D	3
8. Developmental work for laser performance standard.	III-C	2
9. Developmental work for ultrasound therapy performance standard.	III-C	2
10. Developmental work for sunlamp performance standard.	III-C	2
11. Continuation of microwave oven enforcement program.	IV-C	3
12. Development of a voltage measuring device for testing of diagnostic x-ray equipment.	II-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
13. Development of an environmentally controlled wave-guide irradiation facility to determine integral doses from continuous wave microwave radiation sources.	IV-B	6
14. Completion of a study of the efficacy of x-ray pelvimetry examinations.	I-B	6
15. Development of the 10-day rule for ionizing radiation exposure.	I-B	1
16. Addition of a patient selection document to the physician Radiological Health Sciences Learning Laboratory.	I-D	6
17. Establishment of regional training committees to identify and coordinate State and local radiological health training needs.	I-D	6
18. Collection of the NEXT program's first year of data.	I-F	6
19. Study on cancer therapy by interstitial and intracavitary radiation.	I-B	6
20. International symposium on radiopharmaceuticals.	I-D	6
21. Continuation of Oxford survey of childhood cancers.	II-A	1
22. Continuation of Radiation Registry of Physicians.	II-A	1
23. Social Security Administration disability study.	II-A	1
24. Study on childhood cancer in relation to pre-natal irradiation of U.S. servicemen's dependents.	II-A	1
25. Study of the use of phototherapy for jaundice in newborns.	III-A	1
26. Study of phototherapy and hyperbilirubinemia.	III-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
27. Study of intense light and visual function.	III-A	1
28. Study of cell processes and light.	III-A	1
29. Study of light and activation of latent tumor viruses.	III-A	1
30. Study of light and carcinogenesis in rodents.	III-A	1
31. Study of phototherapy for jaundice of the newborn.	III-A	1
32. Hospital surveys of phototherapy use and obstetric ultrasound.	III-B	1
33. Feasibility study of adverse effects of fetal exposure to ultrasound.	III-A	1
34. Study of embryological effects from ultrasound exposure.	III-A	1
35. Development of automated ultrasonic exposure facility.	III-F	6
36. Study of effects of ultrasound on the clotting mechanisms.	III-A	1
37. Neurobehavioral effects of microwave radiation in primates studies.	IV-A	1
38. Study of developmental effects of microwave radiation.	IV-A	1
39. Study of biophysical characterization of microwave biological effects.	IV-A	1
40. Study of genetic and chromosomal effects of microwave irradiation.	IV-A	1
41. Study of microwave cataractogenesis.	IV-A	1

LEGEND

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LEGEND

I - Ionizing Radiation - Use Control

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D - Education/Training

E - Federal/State Relations

F - Other

A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1973

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of proposed cabinet x-ray performance standard.	II-C	2
2. Continuation of TV receiver enforcement program.	II-C	3
3. Continuation of cold-cathode gas discharge tube enforcement program.	II-C	3
4. Developmental work toward laser performance standard.	III-C	2
5. Continuation of microwave oven enforcement program.	IV-C	3
6. Full operation of electrical and ionizing radiation calibration facilities.	II-B	6
7. Issuance of final report on test methods for diagnostic x-ray equipment.	II-B	6
8. Continuation of TV receiver testing.	II-C	3
9. Development of diagnostic x-ray image analysis capacity.	II-B	6
10. Expansion of facilities and capabilities of laser laboratory.	III-B	6
11. Preliminary study of laser safety goggles.	III-B	6
12. Survey of selected facilities concerning use and performance of ultrasonic therapy equipment.	III-B	6
13. Development of a portable ultrasonic radio meter.	III-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
14. Evaluation of new microwave oven leakage detectors.	IV-B	6
15. Completion of data collection on medical products and radiofrequency interference.	IV-B	6
16. Study of external fields around microwave diathermy applicators.	IV-B	6
17. Study of efficacy of x-ray pelvimetry examinations.	I-B	6
18. Initiation of a long-term agreement with the American College of Radiology to sell the physician's Radiological Health Sciences Learning Laboratory.	I-D	6
19. Sale of physician Learning Laboratory to 25 medical schools.	I-D	6
20. Marketed three packaged training programs for x-ray technologists.	I-D	6
21. Conducted a pilot educational/awareness campaign on radiation protection for x-ray technologists.	I-D	6
22. Radiological health training courses for x-ray technologists.	I-D	6
23. Developmental work for the Dental Exposure Normalization Technique (DENT) program completed.	I-D	6
24. Clinical evaluation of Xenon^{133} for performing ventilation and perfusion studies.	I-B	6
25. Study of status and future manpower needs of physicists in medicine in the U.S.	I-B	6
26. Continuation of the Radiation Registry for Physicians.	II-A	1
27. Feasibility study of x-ray induced breast cancer conducted.	II-A	1
28. Oxford survey of childhood cancers performed.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
29. Continuation of cooperative thyrotoxicosis therapy followup study.	II-A	1
30. Continuation of study on effects of fallout on the thyroid gland of children.	II-A	1
31. Continuation of long-term study on effects of radiation exposure to beagles at pre- and post-natal ages.	II-A	1
32. Study of relationship of enzyme activity and protein synthesis changes and morphological changes observed in developing rats.	II-A	1
33. Development of mathematical dose models for estimating bone marrow doses.	II-A	1
34. Study of effects of different (light) radiations on animal-virus mammalian cell inter-actions.	III-A	1
35. Analysis of the relation between intermediate levels of bilirubinemia at birth and mental and physical impairment up through four or more years of age.	III-A	1
36. Hospital survey of phototherapy use.	III-B	1
37. Study of radiation effects on virus mammalian cell interactions.	III-A	1
38. Development of a biological research program directed at hazards relating to ultrasound.	III-A	1
39. Development of an ultrasound exposure laboratory.	III-A	1
40. Continuation of hospital survey of use of diagnostic ultrasound.	III-B	1

Activity	Program Area (see legend below)	Matrix Column Reference
41. Development of a model by which tissue dose can be calculated predictively from the standpoints of known complex dielectric constants of various tissues, volume of tissue and irradiation frequency.	IV-A	1
42. Study of genetic and chromosomal effects of microwave radiation.	IV-A	1
43. Study of microwave cataractogenesis.	IV-A	1
44. Study of biochemical and morphological effects of microwave radiation.	IV-A	1
45. Study of sensory and neurological effects of microwaves.	IV-A	1

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I - Ionizing Radiation - Use Control

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A SUMMARY OF THE FOOD AND DRUG ADMINISTRATION'S RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1972

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of final diagnostic x-ray equipment performance standard.	II-C	2
2. Developmental work for cabinet x-ray performance standard.	II-C	2
3. Continuation of TV receiver enforcement program.	II-C	3
4. Continuation of cold-cathode gas discharge tube enforcement program.	II-C	3
5. Continuation of microwave oven enforcement program.	IV-C	3
6. Initiation of State assistance in providing microwave oven inspection data to FDA.	IV-C	3
7. Completion of electrical calibration facilities in addition to improved ionizing radiation calibration facilities.	II-B	6
8. Development of instrumentation and apparatus to determine compliance with provisions of the diagnostic x-ray equipment performance standard.	II-B	6
9. Studies of three dental radiographic positioning devices.	II-B	6
10. Studies of x-ray films/screens.	II-B	6
11. Cintinuation of laboratory testing of TV receivers.	II-C	3
12. Life-testing of high voltage rectifiers conducted.	II-C	3

Activity	Program Area (see legend below	Matrix Column Reference
13. Developmental work toward calibration and measurement facilities to determine potential biological hazard (light and sonic radiation)	III-B	6
14. Continuation of portable ultrasonic intensity measurement system evaluations.	III-B	6
15. Work with NBS on improving calibration capabilities to insure greater accuracy for laser and other light measuring instruments.	III-B	6
16. Continuation of microwave oven endurance testing.	IV-C	3
17. Continuation of research on the effects of RF and microwave interference on implanted cardiac pacemakers.	IV-B	6
18. Radiological health training courses.	I-D	6
19. Development of packaged training programs.	I-D	6
20. Field testing of Radiological Health Sciences Learning File for physicians.	I-D	6
21. Development of a prototype male gonad shield.	I-B	6
22. Pilot study of the Nationwide Evaluation of X-Ray Trends (NEXT) program.	I-F	6
23. Development of a Technetium^{99m} macro-aggregated albumin kit.	I-B	6
24. Clinical evaluation of I^{123} for thyroid diagnosis performed.	I-B	6
25. Study of x-ray effects on development and function of central and peripheral nervous systems.	II-A	1
26. Study of effects of pre-natal x-ray exposure.	II-A	1
27. Study of long-term effects of radiation exposures on beagles at different pre- and post-natal ages.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
28. Study of effects of partial body irradiation.	II-A	1
29. Study of radiation-induced cocarcinogenesis.	II-A	1
30. Study of x-ray induced amyloidosis in Chinese hamsters.	II-A	1
31. Study of effects of x rays and UV in animal virus-mammalian cell interactions.	II/III-A	1
32. Development of Social Security Administration Disability standards.	II-A	1
33. Continuation of cooperative thyrotoxicosis therapy followup study.	II-A	1
34. Study of effects of x-ray exposure on the fetus.	II-A	1
35. Study of effects of diagnostic I^{131} in children.	II-A	1
36. Continuation of Radiation Registry of Physicians.	II-A	1
37. Study of the effects of different (light) radiations on animal viruses.	III-A	1
39. Experimental biological research for sonic products and devices.	III-A	1
40. Study of the feasibility to evaluate long-term effects in children of diagnostic use of ultrasound.	III-A	1
41. Hospital survey of use of diagnostic ultrasound.	III-B	1
42. Continuation of the followup study of radar workers.	IV-A	1
43. Continuation of the parental irradiation exposure and Down's Syndrome study.	IV-A	1

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A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1971

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of proposed diagnostic x-ray equipment performance standard.	II-C	2
2. Developmental work for cabinet x-ray performance standard.	II-C	2
3. Continuation of TV receiver enforcement program.	II-C	3
4. Initiation of enforcement program for cold-cathode gas discharge tubes.	II-C	3
5. Initiation of a microwave oven enforcement program.	IV-C	3
6. Survey of industrial microwave heating equipment.	IV-C	3
7. Continuation of Bremsstrahlung radiation study to support TV receiver compliance testing.	II-B	6
8. Upgrading of x-ray survey instrument calibration services.	II-F	6
9. Completion of test procedures for compliance testing of diagnostic x-ray equipment.	II-C	6
10. Laboratory tests of TV receivers.	II-C	3
11. Investigation into x-ray emission characteristics of TV tubes.	II-C	3
12. Testing of high voltage vacuum switches.	II-B	6
13. Completion of industrial x-ray equipment testing.	II-C	3

Activity	Program Area (see legend below)	Matrix-Column Reference
14. Developmental work for calibration facility for diagnostic and therapeutic ultrasonic medical equipment.	III-B	6
15. Developmental work for portable ultrasonic intensity measurement systems.	III-B	6
16. Development of a portable laser hazard meter.	III-B	6
17. Development of a scanning instrument for measuring laser characteristics.	III-B	6
18. Continuation of work toward a test procedure to evaluate microwave oven interference with cardiac pacemakers.	IV-B	6
19. Compliance testing of microwave ovens.	IV-C	3
20. Expansion and improvements in endurance testing of microwave ovens.	IV-C	3
21. Radiological health training courses.	I-D	6
22. Development of new training courses in microwave instrumentation and survey techniques, lasers, nuclear medicine, etc.	I, II, IV-D	6
23. Radiological health training courses for chiropractors.	I-D	6
24. Completion of report on the health hazards for radioactive materials not regulated by AEC.	I-B	6
25. Establishment of a nuclear medicine laboratory to evaluate benefit/risk of nuclear medicine procedures.	I-B	6
26. Study of radiation effects of organ systems in larger mammals.	II-A	1
27. Study of in-utero and immunological effects of radiation.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
28. Study of age sensitivity and long-term effects of Sr^{89} in cats.	II-A	1
29. Study of effects of x-irradiation on virus-mammalian cell interactions.	II-A	1
30. Study of mammary tumors: a search for viral etiology and immune suppression by x-radiation.	II-A	1
31. Study of the effects of the fetus of x-ray exposure.	II-A	1
32. Maintenance of the Radiation Registry for Physicians.	II-A	1
33. Continued PHS support of the Atomic Bomb Casualty Commission.	II-A	1
34. Continuation of Utah thyroid disease surveillance study.	II-A	1
35. Study of the effects of radiation in virus mammalian cells interactions.	III-A	1
36. Study on the biological effects of ultrasound.	III-A	1
37. Study conducted to develop instrumentation and methodologies for the determination of microwave exposure and dose distributions in biological materials.	IV-A	1
38. Investigations into microwave thermal distribution in the eye.	IV-A	1
39. Study on the in-utero effects of microwaves.	IV-A	1
40. Study of the molecular effects of microwaves.	IV-A	1
41. Followup study of radar workers.	IV-A	1
42. Continuation of the study on pre-natal radiation and Down's syndrome.	IV-A	1

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I - Ionizing Radiation - Use Control	A - Biological Effects Research
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A SUMMARY OF
THE FOOD AND DRUG ADMINISTRATION'S
RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1970

Activity	Program Area (see legend below)	Matrix Column Reference
1. Publication of cold-cathode gas discharge tube performance standard.	II-C	2
2. Initiation of TV receiver standard enforcement program.	II-C	3
3. Publication of regulations for record-keeping, import requirements, and defective products (ionizing radiation).	II-C	2
4. Publication of regulations for record-keeping, import requirements and defective products (light and sonic radiation).	III-C	2
5. Publication of final microwave oven standard.	IV-C	2
6. Nationwide survey of microwave ovens.	IV-C	3
7. Publication of regulations for record-keeping, import requirements, and defective products (RF microwave).	IV-C	2
8. Study of Bremsstrahlung radiation to support compliance and testing of TV receivers.	II-B	6
9. Adoption of automatic data acquisition system.	II-F	6
10. Laboratory testing of TV receivers.	II-C	3
11. Laboratory testing of TV receiver components.	II-C	3
12. Study of TV projection systems.	II-B	6
13. Development of x-ray detection instrument for TV service technicians.	II-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
14. Establishment of survey instrument calibration protocol.	II-B	6
15. Testing of industrial x-ray equipment.	II-B	6
16. Establishment of facility for calibrating microwave survey instruments.	IV-F	6
17. Development of an inexpensive electronic readout.	IV-B	6
18. Study of characteristics of diode detectors for use in microwave survey instruments.	IV-B	6
19. Development of a testing program to determine the susceptability of cardiac pacemakers to electromagnetic interference.	IV-B	6
20. Survey of microwave ovens from major manufacturers.	IV-C	3
21. Field and laboratory testing of microwave oven leakage radiation.	IV-C	3
22. Evaluation of microwave oven distribution by chemical methods.	IV-B	6
23. Initiation of life-test program for domestic and commercial microwave ovens.	IV-C	3
24. Comparison of several types of microwave radiation survey instruments.	IV-B	6
25. Radiological health training courses.	I-D	6
26. Research studies concerning cyclotron productions of I^{131}.	I-B	6
27. Survey of radionuclide use in medicine.	I-B	6
28. Development of Radiological Health Handbook.	I-D	6
29. Continuation of the cooperative thyrotoxicosis therapy followup study.	II-A	1
30. Study of cellular repair of x-ray damage during the cell cycle.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
31. Virological, hormonal and immunological characterization of radiation-induced mammary tumors.	II-A	1
32. Study of the effect of age or radiation-induced thyroid tumors.	II-A	1
33. Study of effect of immunosuppression on radiation-induced cancer.	II-A	1
34. Study of effects of diagnostic I^{131} in children.	II-A	1
35. Surveillance of children in Utah possibly exposed to I^{131} from weapons testing.	II-A	1
36. Study of fetal irradiation.	II-A	1
37. Study of paternal exposure to radar and Down's Syndrome.	II-A	1
38. Study of mortability and morbidity patterns of patients treated for hyperthyroidism.	II-A	1
39. Study of mental and other effects of scalp x-irradiation for tinea capitis.	II-A	1
40. Establishment of a Radiation Registry for Physicians.	II-A	1
41. Study of effects of UV radiation on viral oncogenic transformation in mammalian cells.	III-A	1
42. Influence of ultrasonic energy on cellular function.	III-A	1
43. Study of the genetic effects of microwave radiation.	IV-A	1
44. Study of the developmental effects of microwaves.	IV-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
45. Study of the biological effects of microwaves.	IV-A	1
46. Study of the neurophysiological effects of microwaves.	IV-A	1

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A SUMMARY OF THE FOOD AND DRUG ADMINISTRATION'S RADIATION PROTECTION ACTIVITIES

Fiscal Year: 1969

Activity	Program Area (see legend below)	Matrix Column Reference
1. Survey of major TV manufacturers.	II-C	3
2. Publication of TV receiver performance standard.	II-C	2
3. Developmental work for diagnostic x-ray equipment performance standard.	II-C	2
4. Developmental work for microwave oven performance standard.	IV-C	2
5. Issuance of variances and amendments to equipment performance standards	*	2
6. Annual meetings of FDA/BRH TEPRSSC advisory committee	*	6
7. Upgrade Council of State Governments' regulations.	*	3
8. Recall of defective products not subject to performance standards.	*	3
9. Monitor electronic product imports.	*	3
10. Review of manufacturers' quality control and testing programs.	*	3
11. Development of a TV survey instrument	II-B	6
12. Development of thermoluminescent dosimetry system for accurately and inexpensively measuring integrated ionizing radiation exposure.	II-B	6
13. Development of an x-ray pulse counter to check performance of x-ray machine timers.	II-B	6

Activity	Program Area (see legend below)	Matrix Column Reference
14. Conduct two studies concerning effects of microwave irradiation of selected organic compounds and thermoluminescent dosimetry material for microwave exposure.	IV-B	6
15. Surveys of far-field emissions from microwave ovens.	IV-B	3
16. Design of a prototype laser hazard meter for measurement of continuous-wave low-power lasers.	III-B	6
17. Radiological health training courses.	I-D	6
18. Radiopharmaceutical symposium.	I-D	6
19. Radiology administrator program.	I-D	6
20. Nuclear medicine technologist training program.	I-D	6
21. Development of radioactive materials reference manual.	I-D	6
22. Initiation of nationwide X-ray Exposure Study.	I-B	1
23. Initiation of fetal irradiation study.	II-A	1
24. Study of delayed effects of scalp x irradiation.	II-A	1
25. Study of in-utero irradiation with high and low energy x rays at various dose rates.	II-A	1
26. Study of effects of x irradiations on enzyme induction and protein synthesis.	II-A	1
27. Study of effects of radiation damage to nucleic acids on rat liver cell function.	II-A	1
28. Study of effects of high and low energy x rays on immunocompetence.	II-A	1
29. Study of chromosome stickiness and division delay in x irradiated cultured cells.	II-A	1

Activity	Program Area (see legend below)	Matrix Column Reference
30. PHS support of the Atomic Bomb Casualty Commission.	II-A	1
31. Cooperative thyrotoxicosis therapy followup study.	II-A	1
32. Study of effects of using I^{131} in children.	II-A	1
33. Initiation of a Radiation Incidents Registry.	**	1
34. Study of diagnostic radiation in short-stay general hospitals.	II-B	1
35. Study of light enhancement of tumor virus transformation.	III-A	1
36. Study of influence of ultrasonic energy on cellular function.	III-A	1
37. Study of prenatal radiation exposure and Down's syndrome.	IV-A	1

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* This activity relates to three FDA program areas: Ionizing Radiation - Products and Devices, Light and Sonic Radiation, and RF Microwave, and should be considered in the category of C (below) - Performance Standards, Compliance and Surveillance, and are carried out on a continuing basis.

** Same as above: this particular activity falls under the category of General Research (B).

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ENVIRONMENTAL PROTECTION AGENCY

Radiation Program and Resource Information, June 6, 1977

I. NON-IONIZING RADIATION

A. Studies to determine human health effects

The program resources have been almost exclusively employed to support intramural, interdisciplinary health effects research at Research Triangle Park, North Carolina. The emphasis has been on the development of RF exposure systems of environmental importance, e.g., FM Radio, UHF-TV, radar, and microwave ovens for use in animal and cellular experimentation. The biological parameters which are investigated include teratology, immunology, spontaneous and learned behavior, cytogenetics, reproductive genetics, biochemical and biophysical effects. The subjects of the investigations range from macromolecular, bacterial, and human cell lines to mice, rats, hamsters, dogs and monkeys.

	Fiscal year—						
	1972	1973	1974	1975	1976	1977	1978, proposed
Positions	24	30	30	30	30	30	30
Extramural (thousands)	$75	$13	$28	$235	$40	$86	$60
Total funds (thousands)	$598	$590	$638	$1,000	$770	$770	$830

B. Collection and/or analysis of health data

The program resources were used to fund a contract with the Southern Research Institute to provide a thorough examination of the possible correlation of an increased incidence of congenital anomalies in children born on a U.S. Army base with a high concentration of operational radars.

	Fiscal year—						
	1972	1973	1974	1975	1976	1977	1978, proposed
Positions							
Extramural (thousands)		$13	$28	$9			
Total funds (thousands)		$13	$28	$9			

C. Collection and/or analysis of environmental data

This program includes measurement of non-ionizing radiation levels in the general environment and calculation, measurement, and evaluation of specific types of sources. The calibration and field testing of a mobile radiofrequency measurements systems were completed in 1975. Data on ambient environmental levels in urban areas were collected; evaluations were also made of several problems related to specific sources or source types. The data are now being studied and population exposure is being computed on the basis of a population locator code.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978, proposed
Positions	4	4	6	6	6	6
Extramural (thousands)				$10		
Total funds (thousands)	$96	$207	$197	$207	$200	$200

II. IONIZING RADIATION

A. Studies to determine human health effects

The program resources were primarily used to support intramural research on the age-sensitivity to bone tumor induction resulting from prolonged ingestion of radiostrontium by cats. Lower level efforts were directed towards the teratogenic, reproductive, behavioral, and premature aging and tumorigenic efforts of continuous exposure to tritium on the rat and tissue distribution, kinetics, hematologic, and late effects of exposure to guinea pigs and rats to krypton-85 gas.

	Fiscal year—						
	1972	1973	1974	1975	1976	1977	1978, proposed
Positions	25	25	9	4	2		
Extramural (thousands)	$195	$195		$200		$28	
Total funds (thousands)	$799	$856	$275	$350	$70	$28	

B. Criteria and standards development

The purpose of this program is to protect, cost-effectively, the health and welfare of man and the environment from adverse effects due to radiation exposure and in balance with the benefits of the particular radiation producing activity. There are potential sources of radiation exposure where existing controls are deficient or non-existent and where there is a need to promulgate generally applicable radiation protection standards to provide this protection. Federal Radiation Guidance is being developed for certain areas where there is a demonstrated need to use the Federal Radiation Council transferred authority. Such guidance to other Federal agencies provides the technical basis for reducing unnecessary radiation exposure and keeping the exposure of the general public "as low as reasonably achievable." Other activities for protecting cost-effectively the health and safety of the public are carried out under the authorities set forth under the Safe Drinking Water Act of 1974, the Ocean Dumping Act of 1972, as amended, and the Federal Water Pollution Control Act of 1972, as amended.

Activities included in this project are:

1. Standards for the normal operation of the uranium fuel cycle promulgated in fiscal year 1977 for planned releases from nuclear facilities;
2. Amendments to the UFC standard for control of carbon-14 planned for FY 1978.
3. Guidance for cleanup and restoration of areas already contaminated with plutonium (fiscal year 1977) and standards for release of plutonium.
4. Guides to limit control of radiation exposure from naturally-occurring radioactive materials. Guides for acceptable levels of radiation in structures built on phosphates lands will be published in fiscal year 1977. Draft guidance will be developed in fiscal year 1978 for mineral and extraction industries and land use.
5. Environmental standards for all classes of radioactive wastes. Standards for disposal of high-level wastes are expected to be completed in fiscal year 1978; standards for low-level wastes and for ocean disposal will be completed in fiscal year 1983 and 1985 respectively.
6. Protective Action Guides are developed for use in emergency response planning for unplanned nuclear releases from fixed facilities.
7. Interim Primary Drinking Water Regulations were published in fiscal year 1976 under the EPA program to develop drinking water regulations to protect public health to the extent cost-effectively feasible.
8. Draft Guidance to reduce does from medical diagnostic radiology without jeopardizing diagnostic effectiveness was developed in fiscal year 1977.
9. Guidance for occupational exposure limits for radiation workers will be published in fiscal year 1977.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978
Positions	39	39	48	50	[1] 59	51
Extramural (thousands)	$350	$115		$125	$2, 177	
Total funds (thousands)	$1, 282	$966	$1, 149	$1, 251	[2] $3, 718	1, 229

[1] Includes 8 overtarget positions.

[2] Includes $2,475,000 overtarget.

C. State/Federal liaison

This project includes staffing of EPA Regional Offices with representatives of the Office of Radiation Programs, the provision of direct assistance to State and local governments, and assistance to other Federal agencies in areas where EPA possesses special capabilities. A program of academic training grants was terminated in 1974. The Regional Office serves as the local point for assistance to States with unique radiation problems, providing technical and program consultation and assistance to States where required; responding to public and Congressional inquiries; stimulating productive functioning of the Regional Training Committees to meet State training needs; and facilitating and coordinating ORP activities with States. Commencing in fiscal year 1976, Regional Offices undertook the review of Environmental Impact Statements for light-water-cooled nuclear power reactors. Headquarters and Regional Offices are involved in the development of emergency response capabilities, including the development, testing, evaluation, modification and maintenance of State emergency response plans, and the publication of a manual for use of Protective Action Guides. States are also supported through the provision of radiochemical analyses of special environmental samples at EPA's two radiation field facilities as requested. EPA's specialized monitoring capabilities are made available to other Federal agences on a cost-reimburseable basis for such activities as launches of SNAP devices for Cape Kennedy.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978
Positions	40	40	42	25	25	25
Extramural (thousands)	[1] $483	[1] $83				
Total funds (thousands)	$1,439	$1,013	$1,000	$613	$650	$728

[1] Academic training grants.

Environmental Radiation Ambient Monitoring System (ERAMS)

D. Monitoring and surveillance

ERAMS is a program for continuing surveillance of radioactivity levels throughout the continental United States, Alaska, Hawaii, and U.S. territories. Through this system, over 7,000 individual analyses are performed annually on samples of air, airborne particulates, deposition, surface and drinking water, milk, and human bones. These samples are collected by State and local health agencies and analyzed at ORP's Eastern Environmental Radiation Facility (EERF) at Montgomery, Alabama. The present ERAMS emphasis is toward identifying trends in the accumulation of long-lived radionuclides in the environment. Therefore, specific analyses are made for uranium-234, uranium-238, plutonium-238, plutonium-239, carbon-14, tritium, strontium-90 and krypton-85. Measurements are also made for gross alpha and beta activity, and the gamma emitters, iodine-131, cesium-137, barium-140, and potassium-40.

Data from ERAMS were previously published in Radiation Data and Reports, however, the Office of Radiation Programs terminated this publication with the December 1974 issue. Since then a quarterly summary of raw data from the National Environmental Radiation Ambient Monitoring System network (which includes a limited amount of surveillance data from States) is reported in Environmental Radiation Data. These compendiums consist mainly of data tabulations without interpretation or discussion. These tabulations will be summarized annually and reported in ORP's report of the Radiological Quality of the Environment. An indepth analysis of ERAMS is being carried out to determine annual averages, to identify trends, to characterize the statistical distributions of data sets, to estimate individual and population doses, and to evaluate error terms for each of these determinations.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978
Positions	22	22	22	16	15	15
Extramural (thousands)						
Total funds (thousands)	$526	$501	$501	$320	$320	$436

E. Medical, diagnostic and therapeutic

EPA's approach in this program is to work cooperatively with other Federal agencies concerned with x-ray exposures to the population. An Interagency Committee, chaired by EPA, has been established to develop guidance applicable to Federal health care programs on optimal procedures to assure that the radiation dose, from exposures, is as low as reasonably achievable while maintaining desirable image-quality and concomitantly to assure the efficacy of such procedures. The FDA/BRH is responsible for programs to reduce unnecessary patient exposure by setting performance standards for medical x-ray equipment.

Detailed guidance for Federal health care programs has been prepared for publication in the Federal Register in fiscal year 1977.

(Resources below are included in the figures cited for Criteria and Standards development.)

	Fiscal year—					
	1973	1974	1975	1976	1977	1978, proposed
Positions	2	2	2	2	2	2
Extramural (thousands)						
Total funds (thousands)	$48	$50	$53	$56	$60	$64

F. Collection and/or analysis of health data

The bulk of these resources were used to provide EPA's contribution to the support of the Atomic Bomb Casualty Commission in Hiroshima, Japan. The function of the ABCC is to gather and analyze data on the health status of survivors of the radiation exposures which occurred to the populations of Hiroshima and Nagasaki. Funds were also provided for an epidemiologic study of the incidence of thyroid tumors in several thousand young adults who had received radioiodine in diagnostic procedures and to support a study on the human cytogenetic effects of exposure to radon gas and its daughter products in homes built on uranium tailings.

	Fiscal year—						
	1972	1973	1974	1975	1976	1977	1978, proposed
Positions	12	9	8	7	1		
Extramural (thousands)	$200	$69	$66	$211			
Total funds (thousands)	$442	$305	$176	$389	$55		

G. Collection and analysis of environmental data

EPA conducts a National dose assessment program to determine the status of environmental radiation data, to analyze these data in terms of individual and population doses, and to provide guidance for improving radiation data. This program also provides information to guide the director of the Office of Radiation Programs by the analysis of radiation trends, identification of radiation problems, and support for establishing radiation protection guidance. This program makes maximum use of available data reported by others; additional data are acquired from EPA's Environmental Radiation Ambient Monitoring System, (reported as a separate project for purposes of this paper) and source related field studies.

Recent efforts include a study to determine ambient radiological air quality in the Ambrosia Lake area of New Mexico; a study to determine the impact of uranium mining and milling industry on ground water quality in the Grants Mineral Belt area of New Mexico; studies to determine remedial actions required at inactive uranium mill sites in the Western United States; and studies to determine radon levels on houses built on land reclaimed from phosphate mining in Florida, as well as sampling fruits and vegetables grown on reclaimed land for possible contamination.

An annual publication, Radiological Quality of the Environment, summarizes individual and population dose data for both ionizing and non-ionizing radiation, providing a comprehensive evaluation of radioactivity in the environment and indicates trends and problems.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978, proposed
Positions	48	48	36	46	47	47
Extramural (thousands)						
Total funds (thousands)	$1,147	$1,276	$823	$888	$965	$1,368

H. Technology assessment

The purpose of the program is to assess nuclear energy applications and documentation for EPA's radiation protection standards and to prepare technical guidance. The programs of other Federal agencies are influenced to assure protection of the environment and public health by review of their environmental impact statements, regulations, and proposed legislation as required by the National Environment Policy Act, Section 309 of the Clean Air Act of 1970, and Section 511 of the Federal Water Pollution Control Act of 1972, as amended. Advanced reactor systems and new applications of nuclear energy are evaluated on a case-by-case basis to learn in the development stage about potential environmental radiation problems. From such assessments EPA's position on the environmental and economic impact will evolve.

Comprehensive technical reviews of environmental impact statements are made for facilities and programs which have a potential radiological impact, so that any environmental problems can be identified in time to modify the facility or program. Engineering studies are pursued on selected aspects of power production, either through nuclear facilities or non-nuclear sources which have the potential for radiation exposure of the environment or the population. Recent issues studied include accident possibilities and siting of nuclear power plants; advanced nuclear technologies such as the liquid metal fast breeder reactor: alternatives for the management of various classes of radioactive wastes; and transportation of nuclear materials.

	Fiscal year—					
	1973	1974	1975	1976	1977	1978
Positions	27	27	37	[1] 40	[1] 40	[1] 40
Extramural (thousands)	$220	$190				
Total funds (thousands)	$865	$778	$902	$1,103	$1,040	$1,164

[1] Includes 7 regional office positions.

Question 1. What changes in jurisdiction between 1968 and 1977 affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer 1. EPA's primary radiation protection responsibilities were vested in the authorities transferred to the Agency by Reorganization Plan Number 3 of 1970. This plan created EPA. The major functions transferred at that time were to:

(a) Establish generally applicable environmental standards for the protection of the general environment from radioactive material (Atomic Energy Act of 1954, as amended).

(b) Advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States (Atomic Energy Act of 1954, as amended). This authority had been previously vested in the President's Federal Radiation Council.

(c) Collect and provide information to the public on environmental levels of radiation (Public Health Act, as amended).

(d) Provide States Assistance (Public Health Service Act, as amended).

In addition to the Reorganization Plan, the Agency is authorized by the National Environmental Protection Act of 1969 to review the environmental impact statements of major Federal actions significantly affecting the quality of the human environment.

Subsequently EPA was authorized to: (a) issue permits for dumping radioactive materials into ocean waters (Marine Protection, Research and Sanctuaries Act), and (b) propose and promulgate primary and secondary drinking water regulations (Safe Drinking Water Act).

Attached to these responses is an appendix which contains an overview of Federal and State Radiation Control Functions and Authorities in major program areas. The information in the appendix will provide a broader concept of radiation protection activities within the Executive Department.

Since its formation, EPA's basic radiation protection authorities have not been affected by the emergence of new agencies. However, on many occasions the extent of the Agency's authority has been challenged by other agencies. For example, the Atomic Energy Commission (replaced by the Nuclear Regulatory Commission (NRC)) and the Energy Research and Development Administration (ERDA) challenged EPA's authority to set a generally applicable environmental standard for the specific facilities in the uranium fuel cycle. This issue was resolved satisfactorily by EPA and NRC and culminated in the issuance of EPA's uranium fuel cycle standards, which are implemented through regulations issued by NRC.

More recent examples of possible overlap of the Agency's authority are those by the Department of Health, Education, and Welfare (DHEW) related to Federal Gudiance in the fields of healing arts and nonionizing radiation and those by the Department of Labor (DOL) in formulating guides for occupational radiation exposure. Pursuant to EPA's Federal guidance responsibility, broad guidance in radiation protection is developed and recommended by the Administrator to the President for his approval. Approved guides then became the basis for regulations promulgated by Federal agencies in accordance with their specific responsibilities. It is in this context that efforts are made to resolve any differences with DHEW and DOL, and in fact, a memorandum of understanding has been signed with DHEW to provide for cooperative efforts in radiation protection for the healing arts. A copy of the memorandum of understanding is attached. (See 42 Fed. Reg. 5123–24, January 27, 1977.)

Question 2. Would you please describe the nature of the contacts between your organization and State groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with State agencies? Is there any confusion concerning respective responsibilities of State and Federal agencies?

Answer 2. The Agency's contact with State groups in the radiation field are achieved through various means. First the 10 Regional Office maintain direct contact with the States in their locality, and each has a staff member designated for radiation protection activities.

A second means is the Conference of Radiation Control Program Directors, Inc. (CRCPD). This organization is sponsored by EPA, NRC and the Food and Drug Administration (FDA) of DHEW. The membership of the Conference consists of State and local radiological control program directors. The objectives of the CRCPD are to:

(a) Promote radiological health in all aspects and phases.

(b) Coordinate radiological health activities of governmental agencies.

(c) Encourage the interchange of experience among radiation control program directors.

(d) Collect and make accessible to all radiation control program directors in official administrative positions such information and data as might be of assistance to them in the proper fulfillment of their duties.

The Federal agencies work closely with the Conference throughout the year to accomplish these objectives. The Agency has found the Conference to be an affective body for assuring coordination between Federal and State radiation control programs.

Attached is a copy of the Interagency Agreement EPA has with FDA to provide support of the CRCPD. FDA has a similar agreement with NRC. This attachment will provide a better understanding of this type of Federal and State coordination.

On several occasions EPA has been requested by a State to assist them in completing a project or performing a study. In these situations EPA coordinates its findings, plans and recommendations with the State authorities.

Two recent examples of State assistance are: The evaluation of the radiological impact of building houses on reclaimed phosphate land in Florida and the evaluation of the radiation problems associated with using mill tailings in building construction of Grand Junction, Colorado. These studies and resulting recommendations were continuously coordinated with State and local health officials.

The Safe Drinking Water Act, which includes radioactivity, allows States to accept responsibility for enforcement upon approval by EPA of the State's plan. EPA is required to assist the States to develop their capability to assume this responsibility. If a State cannot or does not accept this responsibility, then EPA is required to implement the Safe Drinking Water Act within that State.

The Office of Radiation Programs (ORP) of EPA operates a nationwide Environmental Radiation Ambient Monitoring System (ERAMS) to provide for the continuing surveillance of radioactive levels throughout the United States and its territories. Through this system, over 7000 individual analyses are performed annually in samples of air, airborne particulates, deposition, surface and drinking water, milk and human bones. These samples are collected by the State and local health agencies. ORP expands its ERAMS operation through the States after nuclear weapons atmospheric tests are conducted.

In another interagency program with the Federal Preparedness Agency, the Bureau of Radiological Health (BRH) of Food and Drug Administration, Energy Research and Development Administration, Department of Transportation, Defense Civil Preparedness Agency, Federal Disaster Assistance Administration and Nuclear Regulatory Commission, EPA advises and assists the States to develop emergency response plans for radiation incidents involving fixed nuclear facilities and transportation.

The above examples represent the various mechanisms employed by the Agency in maintaining contact with State and local officials. While these mechanisms tend to minimize confusion concerning the responsibilities of State and Federal agencies, there are occasions when confusion exists. An example of one such occasion is the responsibility for financing the cleanup of abandoned uranium mill tailings piles in the West. There existed no mechanism for the Federal government to implement a program of cleanup and restoration. Similarly, the States involved did not consider the problem their responsibility. Consequently, ERDA and EPA at the request of the Joint Committee on Atomic Energy were required to analyze the problem and determine a feasible solution. There remains some confusion between the States and the Federal government over which one will finance the cleanup and restoration of these lands.

Another example of confusion of authority is the question of Federal or State responsibility for solving the various problems associated with the high-level radioactive waste at West Valley, New York. These problems have not been resolved as of this date.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer 3. Because radiation protection involves exposure arising from a variety of sources, it is extremely important that public health and environmental protection measures be derived from a basic source of guidance and not reflect as a basic premise other goals, such as energy production or radiation application in medicine. Within the Federal sector such a source exists in the Federal Radiation Council authority held by the EPA Administrator. Full recognition and utilization of this authority, complemented by appropriate regulation by Federal agencies having regulatory responsibilities, could assure the required public health and environmental protection. Thus, after Federal Radiation Guidance has been promulgated, other agencies of the Federal government charged with responsibilities for regulation of specific areas of radiation protection must implement appropriate control and enforcement programs.

At the present time there are some areas where regulatory and legislative gaps may exist. These include the control of radiation from (a) tailings from inactive uranium milling, phosphate and other extraction facilities, (b) various sources of enhanced exposure from naturally-occurring radioactive materials, and (c) ambient levels of non-ionizing radiation. Further analyses of these problems are required before the specific need for legislation can be determined.

Resources are never wholly adequate to meet problem assessment and regulation development needs for any EPA regulatory program. However, we feel that proper priority attention can generally be handled within present funding levels.

Question 4. What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal radiation agency?

Answer 4. Consolidation of all Federal radiation protection programs into one Federal radiation agency has some merit. Through such an agency jurisdictional disputes and program duplication could conceivably be eliminated and there would exist one focal point in the Administration concerning radiation protection policies. In addition, such an agency could also conceivably more effectively compete for resources, eliminate multiple agency reporting requirements now imposed on State governments, and simplify Federal-State government relationships.

However, there are alternatives other than consolidation into one Federal agency. For example, EPA's Federal Radiation Council (FRC) authority could be strengthened through encouraging Federal agency cooperation. The FRC authority currently has the broad and comprehensive responsibility to serve as a focal point for national radiation protection policies and for developing recommendations for Federal guides. It could be expanded to include mandates for better review of national protection programs, monitoring and environmental and public health assessments. Other Federal agencies would retain their regulatory responsibilities and implement regulations within their legislative mandates to insure compliance with EPA's standards and guidelines.

EPA SUBMISSION

APPENDIX 1

FEDERAL AND STATE RADIATION CONTROL FUNCTIONS AND AUTHORITIES IN MAJOR PROGRAM AREAS

A. FUNCTION

Advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States.

BASIC AUTHORITY

Atomic Energy Act of 1954, as amended.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

B. FUNCTION

Regulation of possession, use, and production of source material, byproduct material, and special nuclear material to provide for the common defense and security and to protect the health and safety of the public.

"Source material" means (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium or (iii) any combination thereof.

"By product material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

"Special nuclear material" means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material determined by the NRC to be special nuclear material; or (2) any material artificially enriched by any of the foregoing.

LIMITATIONS

This authority does not provide control of naturally-occurring radioactive material, such as radium, not specifically listed as "source material," or of uranium or thorium in concentrations less than that specified, or of radioactive material produced by an accelerator or other means not specified. In addition, certain uses of uranium and thorium are exempt from regulation (10CFR40).

BASIC AUTHORITY

Atomic Energy Act of 1954, as amended.

AUTHORITY TRANSFERRED BY

Energy Reorganization Act of 1974 (PL 93-438).

RESPONSIBLE AGENCY

Nuclear Regulatory Commission (through agreement with NRC, certain States have assumed specific regulatory authorities from NRC).

C. FUNCTION

Consider the environmental impact of high voltage transmission lines.

LIMITATIONS

Applicable only to such lines originating at nuclear generating plants.

BASIC AUTHORITY

Atomic Energy Act of 1954, as amended (licensing of plants). National Environmental Policy Act of 1969.

AUTHORITY TRANSFERRED BY

Energy Reorganization Act of 1974 (PL 93-438).

RESPONSIBLE AGENCY

Nuclear Regulatory Commission.

D. FUNCTION

Regulate the presence of radioactive materials in or the use of radiation with foods and drugs. Regulate the use of radiopharmaceuticals.

BASIC AUTHORITY

Food Additives Amendment of 1958 (PL 85-929). Federal Food, Drug and Cosmetics Act and Sec. 351 of Public Health Service Act.

RESPONSIBLE AGENCY

DHEW (FDA).

E. FUNCTION

Those functions vested by law in the Secretary of HEW or the DHEW which were administered through the Environmental Health Service and carried out by the Bureau of Radiological Health insofar as they pertain to regulation of radiation from consumer products, including electronic product radiation, and research, technical assistance, and training related to regulation of radiation from consumer products.

LIMITATIONS

Regulatory authority exists only for control of electric product radiation, not for radiation from all consumer products.

BASIC AUTHORITY

Public Health Service Act, as amended (section ——) including the Radiation Control for Health and Safety Act of 1968 (PL 90-602).

AUTHORITY TRANSFERRED BY

Authority specifically retained in DHEW by Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

DHEW (FDA-BRH).

F. FUNCTION

Those functions vested by law in the Secretary of HEW or the DHEW which were administered through the Environmental Health Service and carried out by the Bureau of Radiological Health insofar as they pertain to occupational exposures to radiation, and research, technical assistance, and training related to occupational exposures to radiation.

LIMITATIONS

No specific regulatory authority related to occupational radiation exposures; only general authorities and functions conferred by the Public Health Service Act would be included.

BASIC AUTHORITY

Public Health Service Act, as amended (section ——).

AUTHORITY TRANSFERRED BY

Authority specifically retained in DHEW by Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

DHEW (FDA-BRH).

G. FUNCTION

Those functions vested by law in the Secretary of HEW or the DHEW which were administered through the Environmental Health Services and carried out by the Bureau of Radiological Health insofar as they pertain to radiation as used in the healing arts, and research, technical assistance, and training related to radiation as used in the healing arts.

LIMITATIONS

No specific regulatory authority for radiation as used in the healing arts except for performance standards to control radiation emissions from electronic products used in the healing arts. General authorities and functions conferred by the Public Health Service Act would be included.

BASIC AUTHORITY

Public Health Service Act, as amended (section ----), including the Radiation Control for Health and Safety Act of 1968 (PL 90-602).

AUTHORITY TRANSFERRED BY

Authority specifically retained in DHEW by Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

DHEW (FDA-BRH).

H. FUNCTION

Establish generally applicable environmental standards for the protection of the general environment from radioactive material. As used herein, standards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

LIMITATIONS

This function derives from the AEC as administered through its Division of Radiation Protection Standards. Hence, it is applicable only to those radioactive materials and/or facilities subject to regulation by the AEC (now NRC). Clarification of this function related to the uranium fuel cycle was provided by the Director of the Office of Management and Budget who wrote on December 7, 1973: "EPA should discontinue its preparations for issuing, now or in the future, any standards for types of facilities; the EPA should continue under its current authority, to have responsibility for setting standards for the total amount of radiation in the general environment from all facilities combined in the uranium fuel cycle, i.e., an ambient standard which would have to reflect AEC's findings as to practicability of emissions controls."

BASIC AUTHORITY

Atomic Energy Act of 1954, as amended.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

I. FUNCTION

1. Research, investigations, training, information, technical assistance, water quality surveillance, grants and contracts.
2. Discharge of any pollutant into navigable waters by any person is unlawful except in compliance with various sections of the FWPCA.
3. Establish effluent limitations for point sources.
4. Discharge of any radiological warfare agent or high-level radioactive waste into navigable waters is unlawful, notwithstanding any other provisions of the Act.
5. Approve State water quality standards which are consistent with the requirements of the FWPCA, or propose and promulgate water quality standards for a State.
6. Develop and publish criteria for water quality.
7. Publish guidelines for effluent limitations.
8. Issue information on identifying and evaluating nonpoint sources of pollution, processes, procedures, and methods to control pollution.
9. Promulgate guidelines establishing test procedures for the analysis of pollutants, monitoring requirements, reporting requirements, enforcement provisions, and funding, personnel qualifications, and manpower requirements for State programs.
10. Publish a list of categories of sources and propose and promulgate regulations establishing Federal standards of performance for new sources within the categories.
11. Publish a list of toxic pollutants or combination of such pollutants; propose and promulgate effluents standards or prohibitions for such pollutants.
12. Right to inspect, monitor, and right of entry.
13. Policy of U.S. that there should be no discharges of hazardous substances into or upon the navigable waters of the U.S., adjoining shorelines, or into or upon the waters of the contiguous zone. Administrator shall develop and promulgate regulations designating as hazardous substances such elements and compounds which, when discharged in any quantity present an imminent and substantial danger to the public health or welfare, including fish, shellfish, wildlife, shoreline, and beaches. The President shall by regulation determine those quantities of any hazardous substannces the discharge of which, at such times, locations, circumstances, and conditions, will be harmful to the public health or welfare of the U.S., including fish, shellfish, wildlife, and public and private property, shorelines, and beaches. Discharge of hazardous substances in harmful quantities as determined by the President is prohibited, except where permitted in quantities and at times and locations or under such circumstances or conditions as the President may, by regulation, determine not to be harmful. (Authority of the President as shown above has been delegated to the Administrator of EPA by E.O. 11735.)
14. Issue permits for the discharge of any pollutant, or combination of pollutants, under certain conditions.

NOTE.—The term "pollutant" means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat . . . discharged into water.

"Toxic pollutant" means those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly through food chains, will, as the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring.

The term "pollution" means the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water.

LIMITATIONS

The following "comment" is included as part of 40 CFR 1, Section 125.1(x):

The legislative history of the Act reflects that the term "radioactive materials" as included within the definition of "pollutant" in section 502 of the Act covers only radioactive materials which are not encompassed in the definition of source, byproduct, or special nuclear materials as defined by the Atomic Energy Act of 1954, as amended, and regulated pursuant to the latter Act. Examples of radioactive materials not covered by the Atomic Energy Act and, therefore, included within the term "pollutant" are radium and accelerator produced isotopes.

This interpretation of the limitations of the EPA authority was challenged by the Colorado Public Interest Research Group, upheld by the lower Court, appealed to and overruled by the U.S. Court of Appeals for the Tenth Circuit, and now will be reviewed by the Supreme Court.

BASIC AUTHORITY

Federal Water Pollution Control Act, as amended.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

J. FUNCTION

1. Research, demonstrations, training, information, grants and contracts.
2. Publish guidelines for solid waste recovery, collection, separation, and disposal systems, which shall be consistent with public health and welfare, and air and water quality standards and adaptable to appropriate land-use plans.
3. Recommend model codes, ordinances, and statutes which are designed to implement purposes of this chapter.
4. Each Executive agency which issues any license or permit for disposal of solid waste shall, prior to the issuance of such license or permit, consult with the Secretary to insure compliance with guidelines recommended and the purposes of this chapter.
5. Submit a comprehensive report and plan for the creation of a system of national disposal sites for the storage and disposal of hazardous wastes, including radioactive, toxic chemical, biological, and other wastes which may endanger public health or welfare.

BASIC AUTHORITY

The Solid Waste Disposal Act, as amended.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

K. FUNCTION

1. Propose and promulgate national primary and secondary drinking water regulations; provides for State primary enforcement responsibilities.
2. Propose and promulgate regulations for State underground injection control program; provides for State primary enforcement responsibilities.
3. Upon receipt of information that a contaminant which is present in or is likely to enter a public water system may present an imminent and substantial endangerment to the health of persons, and that appropriate State and local authorities have not acted to protect the health of such persons, may take such actions as he may deem necessary in order to protect the health of such persons, including issuing such orders as may be necessary to protect the health of persons who are or may be users of such system, and commencing a civil action for appropriate relief, including a restraining order or injunction.
4. Research, technical assistance, information, training of personnel, and grants.

LIMITATIONS

Public water system is defined as having at least 15 service connections or regularly serves at least 25 individuals.

BASIC AUTHORITY

Safe Drinking Water Act (PL 93–523) amends the Public Health Service Act by adding a new Title XIV—Safety of Public Water Systems.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Environmental Protection Agency.

L. FUNCTION

1. Publish a list of air pollutants which have an adverse effect on public health and welfare; issue air quality criteria for each listed pollutant; propose and promulgate national primary and secondary air quality standards for each pollutant.
2. Publish a list of categories of stationary sources which may contribute significantly to air pollution which causes or contributes to the endangerment of public health or welfare; propose and promulgate Federal standards of performance for new sources within a category.
3. Publish a list of hazardous air pollutants (air pollutants to which no ambient air quality standard is applicable and which in the judgment of the Administrator may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness); propose and prescribe emission standards for such pollutants.
4. Upon receipt of evidence that a pollution source or combination of sources is presenting an imminent and substantial endangerment to the health of persons, and that appropriate State or local authorities have not acted to abate such sources, may bring suit to immediately restrain any person causing or contributing to the alleged pollution to stop the emission of air pollutants causing or contributing to such pollution or to take such other action as may be necessary.
5. Review and comment in writing on the environmental impact of any matter relating to duties and responsibilities granted pursuant to the Clean Air Act or other provisions of the authority of the Administrator, contained in any (a) legislation proposed by any Federal department or agency, (b) newly authorized Federal projects for construction and any major Federal agency action other than a project for construction to which section 102(2)(c) of PL 91–190 applies, and (c) proposed regulations published by any department or agency of the Federal Government. Such written comment shall be made public at the conclusion of any such review. In the event the Administrator determines that any such legislation, action, or regulation is unsatisfactory from the standpoint of public health or welfare or environmental quality, he shall publish his determination and the matter shall be referred to the Council on Environmental Quality.

LIMITATIONS

Certain exemptions may be granted by the President in the interest of National security. The Clean Air Act shall not be construed as superseding or limiting the authorities and responsibilities, under any other provision of law, of the Administrator or any other Federal officer, department, or agency.

BASIC AUTHORITY

The Clean Air Act, as amended.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

M. FUNCTION

Those functions vested by law in the Secretary of HEW or the DHEW which were administered through the Environmental Health Service, including the functions exercised by the Bureau of Radiological Health.

LIMITATIONS

This authority does not include those functions carried out by the Bureau of Radiological Health insofar as they pertain to (A) regulation of rediation from consumer products, including electronic product radiation, (B) radiation as used in the healing arts, (C) occupational exposures to radiation, and (D) research, technical assistance, and training related to (A), (B), and (C). No regulatory authority is included.

BASIC AUTHORITY

Public Health Service Act, as amended.

Pertinent general authorities and functions conferred by the Public Health Service Act include the following:

A. Research and Investigations

1. Conduct and promote coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physicial and mental diseases and impairments of man.
2. Encourage, cooperate with, and render assistance to other appropriate public authorities, scientific instiutions, and scientists in the conduct of the foregoing.
3. Collect and make available information on such research and other activities.
4. Make available technical advice and assistance on the application of statistical methods to experiments, studies, and surveys.
5. Award grants and contracts for research, investigations, and studies.
6. Adopt such additional means as necessary and appropriate to carry out purposes of this section.

B. National Health Surveys and Studies

1. Make, by sampling or other appropriate means, surveys and special studies of the population to determine the extent of illness and disability and related information such as (a) number, age, sex, and occupation or activities of persons afflicted with chronic or other diseases or injury; (b) economic and other impacts of such conditions; and (c) environmental and social health hazards.
2. Develop and test new or improved methods for obtaining current data on illness and disability and related information.
3. Undertake research, development, demonstration, and evaluation relating to design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels.
4. Make available the results of surveys and studies.

5. Authorized and directed to cooperate and consult with other interested Federal Departments or agencies and with State health departments.

C. Federal-State Cooperation

1. Assist States and their political subdivisions in the prevention and suppression of communicable diseases.
2. Cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations.
3. Advise the several States on matters relating to the preservation and improvement of the public health.
4. Encourage cooperative activities between States with respect to comprehensive and continuing planning as to current and future health needs and the establishment and maintenance of adequate public services.
5. Train personnel for State and local health work.
6. May, at request of appropriate State or local authority, extend temporary assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance, and may require reimbursement for such aid.

D. Publication of Health Educational Information

Issue information related to public health for the use of the public.

AUTHORITY TRANSFERRED BY

Reorganization Plan No. 3 of 1970.

RESPONSIBLE AGENCY

Environmental Protection Agency.

N. FUNCTION

With respect to prevention, control, and abatement of environmental pollution at Federal facilities—

A. Provide technical assistance and advice.
B. Maintain review of Federal facilities' compliance with specified standards.
C. Provide liaison to assure that Federal actions are coordinated with State, interstate, and local programs.
D. Mediate conflicts between Federal agencies and State, interstate, or local agencies.
E. Develop in consultation with heads of other Federal agencies a coordinated strategy for Federal facility compliance with applicable specified standards, and issue such regulations and guidelines as are deemed necessary.
F. Maintain review of implementation of this order and report to the President on the progress of Federal agencies in implementing this order.

The radiation standards specified in this order include Federal guidance on radiation and generally applicable environmental radiation standards promulgated or recommended by the Administrator and adopted in accordance with the Atomic Energy Act, as amended (42 U.S.C. 2011), and rules, regulations, requirements, and guidelines on discharges of radioactivity as prescribed by the Atomic Energy Commission.

LIMITATIONS

Applicable only to Federal facilities.

BASIC AUTHORITY

Executive Order 11752.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Environmental Protection Agency.

O. FUNCTION

Dumping of radiological warfare agents or high-level radioactive waste into ocean waters is prohibited. Administrator may issue permits for dumping into ocean waters of other materials, including radioactive materials, when determined that such dumping will not unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities.

BASIC AUTHORITY

Marine Protection, Research and Sanctuaries Act.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Environmental Protection Agency.

P. FUNCTION

1. Conduct research, studies, and investigations on the safety of consumer products; test consumer products.
2. Promulgate consumer product safety standards, including requirements as to performance, composition, contents, etc., or requirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions.
3. Under certain conditions may declare a consumer product a banned hazardous product.
4. May file action in court for seizure of an imminently hazardous consumer product.
5. May require manufacturer of any new consumer product to furnish notice and a description of such product to the Commission before its distribution in commerce.
6. May require product certification and labeling.
7. Carry out functions of the Federal Hazardous Substances Act.

LIMITATIONS

The Commission has no authority to regulate any risk of injury associated with a consumer product if such risk could be eliminated or sufficiently reduced by actions taken pursuant to the Occupational Safety and Health Act of 1970, the Atomic Energy Act of 1954, the Clean Air Act, or the Radiation Control for Health and Safety Act.

BASIC AUTHORITY

Consumer Product Safety Act (PL 92-573). Federal Hazardous Substances Act.

AUTHORITY TRANSFERRED BY

Consumer Product Safety Act transferred miscellaneous existing authorities to the Commission.

RESPONSIBLE AGENCY

Consumer Product Safety Commission.

Q. FUNCTION

Establishment of an occupational safety and health program, including promulgation of standards, enforcement, conduct of research, training, and cooperative programs with States.

LIMITATIONS

Does not apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended, exercise statutory atuhority to prescribe or enforce standards or regulations affecting occupational safety or health.

BASIC AUTHORITY

Occupational Safety and Health Act of 1970 (PL 91-596).

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Department of Labor (OSHA).

R. FUNCTION

Set health and safety standards for miners, including regulation of exposure of uranium miners to radon and radon daughters in mines.

BASIC AUTHORITY

Federal Metal and Non-Metallic Mine Safety Act (PL 89-577).

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Department of the Interior (Bureau of Mines).

S. FUNCTION

Regulate for the safe transportation in interstate and foreign commerce of all hazardous materials, including radioactive materials, by all modes of transport, highway, rail, or water, and by all means.

LIMITATIONS

Postal shipments are under the jurisdiction of the U.S. Postal Service and are therefore excluded from this authority.

BASIC AUTHORITY

Department of Transportation Act (PL 89-670).

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Department of Transportation (FAA, Federal Highway Administration, Federal Railroad Administration, and U.S.C.G.).

T. FUNCTION

Regulate radiofrequency and microwave sources used in communications, primarily based on consideration of interference.

LIMITATIONS

No statutory authority to control radiation health hazards, but could take this into account in the licensing procedures.

BASIC AUTHORITY

FCC—Communications Act of 1934, as amended, and Communications Satellite Act of 1962. OTP—Reorganization Plan No. 1 of 1970, and Executive Order 11556.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

1. Federal Communications Commission (Civilian source).
2. Office of Telecommunications Policy (Government source).

U. FUNCTION

Regulate high voltage transmission lines.

LIMITATIONS

Applicable only to such lines originating at hydroelectric and pumped storage generating plants.

BASIC AUTHORITY

Federal Power Act, as amended.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Federal Power Commission.

V. FUNCTION

Comment on the environmental impact statements of all Federal agency recommendations or reports on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment.

LIMITATIONS

None.

BASIC AUTHORITY

National Environmental Policy Act of 1969.

AUTHORITY TRANSFERRED BY

N/A.

RESPONSIBLE AGENCY

Any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved.

W. FUNCTION

Responsible for the radiation health and safety and environmental protection at Energy Research and Development Administration (ERDA) owned and operated and ERDA contractor operated facilities; engaging in and supporting environmental, biomedical, physical, and safety research related to the development of energy sources and utilization technologies.

LIMITATIONS

Certain classes of ERDA facilities are subject to regulatory control by the Nuclear Regulatory Commission, as defined in Section 202 of the Energy Reorganization Act of 1974.

BASIC AUTHORITY

Atomic Energy Act of 1954, as amended. Energy Reorganization Act of 1974.

AUTHORITY TRANSFERRED BY

Energy Reorganization Act of 1974.

RESPONSIBLE AGENCY

Energy Research and Development Administration.

STATE RADIATION CONTROL AUTHORITIES

In addition to Federal radiation control authorities, most of the States possess authority to control certain aspects of radiation. Many of the Federal statutes either mandate that States promulgate and enforce regulations, or permit the Federal authority to be delegated, through agreements, to the States. Where there is no Federal regulatory authority to control certain aspects of radiation, most of the States have enabling statutes and regulatory programs for such cotnrol.

Federal statutes that either mandate establishment of State regulatory programs or permit delegation to States include the following: Safe Drinking Water Act. Occupational Safety and Health Act of 1970. Federal Water Pollution Control Act, as amended. Atomic Energy Act of 1954, as.amended. Clean Air Act as amended.

As of June 30, 1974, a total of 47 States and Puerto Rico have enacted specific laws providing for the regulation of ionizing radiation. In the other States and the District of Columbia, authority for some aspects of radiation protection is assumed under general public health laws. State programs generally encompass regulation of X-ray facilities and use, all radioactive materials not under the control of the Nuclear Regulatory Commission, and for those States who have agreed to do so, regulation of radioactive materials formerly under the control of the Nuclear Regulatory Commission.

Pursuant to Section 274 of the Atomic Energy Act of 1954, as amended, the Nuclear Regulatory Commission may enter into agreements with States providing for the discontinuance of the regulatory authority of the Commission with respect to one or more of the following materials within the State:

1. byproduct materials;
2. source materials; and
3. special nuclear materials in quantities not sufficient to form a critical mass.

During the duration of such agreement, the State has the authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards. As of December 31, 1974, 25 States have entered into such an agreement and now conduct a regulatory radiation control program for these materials.

As of June 30, 1973, 16 States had enacted legislation providing for the regulation of nonionizing radiation and four States have specific legislation for the registration of laser devices. In addition, five States and Puerto Rico have specific laws which establish minimum standards for the education, training, and experience of certain user groups that apply ionizing radiation to human beings for diagnostic or therapeutic purposes.

In an effort to achieve compatibility and some degree of uniformity among State radiation control programs, a document entitled "Suggested State Regulations for Control of Radiation" was published by the Council of State Governments in 1962 with the assistance of the U.S. Atomic Energy Commission and the U.S. Public Health Service, and periodically revised and updated. The Office of Radiation Programs, EPA, now participates in the revision effort in cooperation with the Nuclear Regulatory Commission, the Food and Drug Administration, the Conference of Radiation Control Program Directors, and the Council of State Governments. Generally most State radiation control regulations have been developed to be compatible with applicable parts of the Suggested State Regulations, but of course vary in comprehensiveness and effectiveness.

INTERAGENCY AGREEMENT BETWEEN THE BUREAU OF RADIOLOGICAL HEALTH FDA AND THE OFFICE OF RADIATION PROGRAMS, EPA

I. PURPOSE

The Conference of Radiation Control Program Directors, Inc., ("CRCPD"), whose membership consists of State and local radiological health program directors, was established in 1968 and incorporated in 1975. This organization was initially sponsored by the Bureau of Radiological Health, DHEW, and is now sponsored jointly by three Federal agencies—the Bureau of Radiological Health (FDA), the Office of Radiation Programs (EPA), and the Nuclear Regulatory Commission (NRC). The purpose of this agreement is to provide the mechanism for EPA to share in the cost of the FDA contract supporting and obtaining the services of the Conference of Radiation Control Program Directors, Inc. This contract is mutually beneficial and jointly funded.

II. SCOPE OF WORK

The objectives of the CRCPD are to promote radiological health in all aspects and phases; to coordinate radiological health activities of governmental agencies; to encourage the interchange of experience among radiation control program directors; and to collect information and data as might be of assistance to them in the proper fulfillment of their duties. The services of the CRCPD are used to assist the Federal agencies in indentification of radiation control problems and in the development and implementation of solutions to these problems. The CRCPD provides an interface between the sponsoring Federal agencies and the State radiation control programs, promoting better Federal-State relations and understanding, and facilitating the interchange and utilization of expertise and knowledge on radiological health problems of national concern.

A detailed scope of work, mutually agreeable to the sponsoring Federal agencies and the CRCPD, will be prepared annually as the basis for the annual contract. The scope of work for the current contract to be partially supported by EPA funds through his LAG, is shown as the attachment to the agreement.

III. PROVISIONS

The sponsoring Federal agencies—BRH (FDA), ORP (EPA), and NRC—shall share the cost of the annual contract approximately equally, with FDA being the lead agency and contracting agency. EPA's share (one-third of the annual contract cost) will be transferred to FDA as an advance for disbursal under the provisions of the FDA–CRCPD contract and shall be used only for funding of this contract.

Through representation on the Project Advisory Group, the EPA Project Officer shall participate in the development of the annual scope of work and any modifications thereto, in the review of work accomplished under the contract, and shall be the principal EPA point of contact for matters relating to this IAG and the CRCPD. As a sponsoring agency, EPA shall receive copies of or have access to all reports, data, proceedings, and other information developed by the CRCPD under the contract.

IV. DURATION OF AGREEMENT

This agreement shall become effective upon the latest date of execution as indicated below, and shall remain in effect indefinitely until terminated by either party upon 90-days written notice to the other party. It will be funded annually by amendment.

V. PROJECT OFFICERS

FDA: 1. John J. Boesen, Director, Program Planning and Evaluation Staff, Office of Associate Director for Administration, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Md. 20852, (301) 443–2797.

2. James W. Miller, D.D.S., Director, Radiation Operations Staff, HFO–106, Division of Field Operations, Executive Director of Regional Operations. 5600 Fishers Lane, Rockville, Md. 20852, (301) 443–4006.

EPA: R. J. Augustine, Ph. D., Regional Liaison, Office of Radiation Programs (AW–458), U.S. Environmental Protection Agency, 401 M. Street, S.W., Washington, D.C. 20460, (202) 755–4894.

VI. FUNDS:

Funds in the amount of approximately one-third of the estimated annual contract cost will be transferred as an advance from EPA to FDA and are to be disbursed only in support of the FDA–CRCPD contract. The total annual contract cost on a calendar year basis will depend on the detailed work scope developed for each year. For CY 1976, the estimated total cost is $100,000. EPA's annual share will be $33,300 of which approximately $25,000 will be transferred to FDA in FY 1976 and the balance, if needed, will be transferred in FY 1977 along with additional funds as required to support the CY 1977 contract. It is anticipated that normally EPA's share of the estimated contract cost will be transferred to FDA early in each fiscal year so that the funds will be available in FDA prior to the beginning of the calendar year to be covered by the FDA contract.

EPA		*FDA*	
Appropriation No	68X0108	Appropriation No	7560600
Account No	647733A999	Account No	6–6997224–R–21028
D.C. No	A00483	D.C. No	22370K–20
O.C	25.70	O.C	25.31

VII. AUTHORITY

The authority under which this agreement is entered into is provided for in the Public Health Service Act, 42 USC 201 et seq.

VIII. AGREED

ENVIRONMENTAL PROTECTION AGENCY,
W. D. ROWE, Ph. D.,
Deputy Assistant Administrator for Radiation Programs.
FOOD AND DRUG ADMINISTRATION,
LLOYD L. SUNDQUIST,
Director, Division of Contracts—Title and Grants Management.

WORK SCOPE CALENDAR YEAR 1976

Chief, Negotiated Contracts Branch.
Division of Contracts and Grants Management.
Thru: Director, Bureau of Radiological Health, Associate Commissioner for Science, Director, Division of Financial Management, Associate Director for Administration, HFX-10, Bureau of Radiological Health.

MEMORANDUM OF NEED: COORDINATE FEDERAL/STATE RADIATION CONTROL ACTIVITIES AND ASSIST IN SOLVING RADIATION CONTROL PROBLEMS

I. STATEMENT OF WORK

The Conference and Radiation Control Program Directors, composed of State and local radiological health program directors, was established in 1968 and incorporated in 1975. This Conference, which initially was sponsored by the Bureau of Radiological Health, is now sponsored jointly by the Food and Drug Administration, Bureau of Radiological Health, the Office of Radiation Programs of the Environmental Protection Agency, and the Nuclear Regulatory Commission.

The purpose of the Conference is to promote radiological health in all aspects and phases; to coordinate radiological health activities of governmental agencies; to encourage the interchange of experience among radiation control program directors; and to collect and make accessible to all radiation control program directors in official administrative positions such information and data as might be of assistance to them in the proper fulfillment of their duties.

The Conference shall:

A. Plan and hold an annual technical meeting of the Conference members and sponsors consisting of a general session, workshops and clinics for the following purposes:

General Sessions.—To present reports on the status of studies conducted during previous years, technical reports on new developments and task force reports of problems defined and assigned as recommended by the workshop reports, Conference, or sponsors.

Workshops.—To study and define identified problems and/or areas of mutual concern in radiation control and recommend action needed to resolve these problems. The workshop reports are submitted to the Conference for cost benefit evaluation and further action. Problems that require extensive study are assigned to a task force comprised of experts in that field for solving.

Clinics.—To demonstrate mutually beneficial techniques, procedures, and systems which have been developed by the sponsoring agencies for Conference members in radiation control.

B. Perform all administrative management functions required for the conduct of the annual technical meeting including site visits and selections, program planning, and facility arrangements.

C. Appoint and arrange for standing task forces to study, evaluate, and develop recommended actions and/or solutions to current identified problems. Reports generated by these task forces will be evaluated by the Executive Committee of the Conference and reported to the participating agencies. All administrative management functions required to support these task forces will be performed by the Conference.

Task forces and their charges for 1975–76 will be:

1. A Task Force on Evaluation and Distribution of Radioactive Sources and Devices Not Manufactured Under the Atomic Energy Act

To develop by March 1976 the criteria needed to perform an adequate evaluation of devices, sealed sources, foils, dials, and matrices which contain naturally occurring or accelerator produced radioactive material and factors regarding their interstate distribution. By means of these criteria to provide a mechanism for State-Federal control of the manufacture and distribution of subject sources and products not covered under the Atomic Energy Act. To further develop uniform criteria for radiologic hazard acceptability and to study the risk-benefit rates of the use of radioactive materials in consumer products or devices.

2. Task Force on Program Criteria

To develop criteria that can be used in the evaluation of the adequacy of a State radiation control program. Such criteria will also consider machanisms whereby it is assured that State programs are compatible with Federal programs in the enforcement of standards and regulations in the achievement of radiation protection.

3. A Task Force on the Measure of Program Effectiveness as Related to Radioactive Materials

To consider methods for, and devise actual procedures for, the measurement effectiveness for radioactive materials control programs. Priority should be given to identifying methods and/or indices for measuring the magnitude of the problem and the impact of the program on the reduction of needless exposure of the public, patient, and occupational worker from medical sources.

4. A Task Force on Nationwide Evaluation of X-ray Trends (NEXT)

To identify optimum components of a survey.

To provide for uniform data control.

To provide a system for assigning program priorities.

To provide a system for measuring program effectiveness.

To categorize and determine the relative frequency of the sources of poor radiographic quality as these exist in practice today.

To develop exposure ranges which can be recommended for use by participating States in aiding facilities in the maintenance of consistent high quality diagnostic radiography with minimal exposure to the patient.

5. A Task Force on State Credentialling Program for Allied Health Operators

To develop guidelines for implementing uniform credentialling system for radiation operators. Such uniform guidelines will provide for national reciprocity.

To study and evaluate the recommendations of Workshop No. 9 (Seventh Annual Conference, Hyannis, Massachusetts) and, where applicable, recommend action or implementation of these recommendations. To coordinate action with the Bureau of Radiological Health, Division of Training and Medical Applications.

6. A Task Force on Suggested State Regulations for the Control of Radiation

To review and update existing Council of State Governments Suggested State Regulations for Control of Radiation.

To recommend to the Conference changes in the existing model regulations.

To develop new regulations deemed necessary because of new technical developments on Federal requirements.

To strive for compatibility with pertinent Federal regulations during the processes of updating, changing, or developing new regulations.

7. A Task Force on Natural Radioactivity Contamination Problems

To provide assistance to the Federal agencies or the field in scoping the problem of contamination by natural radioactivity.

To assist in developing appropriate guidance and criteria.

To assess the impact of contamination by radioactivity in the environment in the Conference member-States.

To serve as a focal point for input of Conference member-States to the program of the Federal agencies.

8. A Task Force on Waste Management

To recommend specific criteria that can be used in defining what properties a material must possess in order to be acceptable for burial in commercial waste disposal sites.

To evaluate the various methods for the solidification of radioactive waste. To present these recommendations in a report from the CRCPD to the sponsoring agencies by September 30, 1976.

To develop these methods and criteria in cooperation with various Federal and/or State agencies having jurisdiction for possible promulgation as Federal and/or State guidelines criteria and regulations.

To serve as a focal point for the Conference with Federal agencies developing standards, regulations, or guidelines in all areas of radio-active waste management.

9. A Task Force on Bonding and Perpetual Care of Nuclear Licensed Facilities

To evaluate the needs for, and find a mechanism for initiating bonding; to coordinate and, where necessary, recommend Federal legislation to achieve this.

To investigate the availability of other viable supplements to bonding.

D. Establish a National Training Coordination Committee to evaluate the training needs of all the States. Review these needs on a regional basis and assess the training requirements that must be approached from the national level to solve problems encountered. Work with the sponsoring or other Federal agencies, universities, manufacturers, or other resources to develop the training needed in radiation control.

E. Appoint ten Regional Training Committees consisting of one member from each State and perform all administrative management functions required for their support to provide a focus for assessing the training needs of individual States, develop an inventory of training resources in radiological health within each State and establish a positive mechanism for communicating these resources to all State and sponsoring Federal agencies.

F. On an annual basis and/or as requested by the sponsors provide information on State and local efforts in achieving and maintaining comprehensive programs to effectively reduce or control population exposure to ionizing and non-ionizing radiation. The reports will include resources expended and activities performed in all aspects of radiation control.

G. Attend Radiation Advisory Committee meetings of supporting agencies to provide State technical experience into the subjects under advisement.

H. Establish technical committees within the Conference to provide guidance and assistance to the sponsoring agencies in developing national programs in radiation control.

I. Submit quarterly and annual reports of work accomplished and cost accounting to the supporting agencies.

II. RELATIONSHIP OF REQUIREMENTS TO FDA AND BUREAU STATUTORY MISSIONS

Contracting with the Conference of Radiation Control Program Directors will further unify the Federal/State partnership in reducing unnecessary exposure of the public to ionizing and non-ionizing radiation by retaining the services of the 500 radiation control specialists in State and local agencies to assist in identification of, resolving and implementing solutions for, radiation control problems pursuant to Sections 301 and 311 of the Public Health Service Act, as amended, and Sections 356 and 357 of Public Law 90–602 and the commensurate authority of the other Federal participating agencies.

It will coordinate State radiation control activities with programs of the sponsors; assist the participating Federal agencies in maintaining a national data bank on radiation control activities and provide technical data and expertise vital to the formulation of regulations, standards, and model legislation.

III. CO-PROJECT OFFICERS

John J. Boesen, Director, Program Planning and Evaluation Staff, Office of Associate Director for Administration, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, Md.

James W. Miller, D.D.S., Director, Radiation Operations Staff, HFO–106, Division of Field Operations, Executive Director of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md.

IV. PROJECT ADVISORY GROUP

The Federal agencies liaison officers listed below will serve on the project advisory group:

Environmental Protection Agency.—Dr. Robertson J. Augustine (Health Physicist), Regional Liaison (AW–558), Office of Radiation Programs, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C.

U.S. Nuclear Regulatory Commission.—Mr. Sheldon A. Schwartz (Engineer), Special Assistant for State Relations, Office of International and State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C.

V. PROSPECTIVE CONTRACTOR

Conference of Radiation Control Program Directors, Inc., 4815 West Markham Street, Little Rock, Ark.

The Contractor's representative will be:

Mr. Frank E. Wilson, Secretary-Treasurer, CRCPD, Bureau of Environmental Health Services, Department of Health, 4815 West Markham Street, Little Rock, Ark.

VI. PROCUREMENT PLANNING

See scope of work.

VII. DURATION OF CONTRACT

January 1, 1976, to December 31, 1976.

VIII. LEVEL OF EFFORT AND FUNDING

The participating Federal agencies shall share the cost equally with FDA the leading agency. Both the Environmental Protection Agency and the Nuclear Regulatory Commission will, through interagency agreement, transfer their costs to FDA for disbursal.

Estimated total cost: $100,000 ($33,333 per Federal agency)

Cost breakout (travel, per diem):	
Nine task forces	$36, 800
National training coordinator	700
Emergency response planning liaison	1, 000
Regional training committee (RTC) meeetings, (10 regions)	8,000
Executive committee meetings	5, 000
Executive commitee attendance at RTC meetings	1 ,000
Annual meeting site visits for 1977, 1978	1, 000
pre-1976 site visit	750
Program planning, 1976 meeting	750
1976 annual meeting, Springfield, Ill	25, 000
Total	80, 000
Estimated 25 percent overhead	20, 000

IX. RELEASE OF INFORMATION BY CONTRACTOR

The release of information developed under this contract will be freely allowed.

ROBERT H. NEILL.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., March 21, 1977.

JAMES W. MILLER, D.D.S.,
Dental Advisor, Office of Medical Affairs (HFX–4), Bureau of Radiological Health, Food and Drug Administration, Rockville, Md.

DEAR DR. MILLER: This letter, upon acceptance by FDA, will constitute an amendment to Interagency Agreement No. EPA–IAG–D6–H968 (FDA No. 224–76–6005). The purpose of this amendment is to (1) include the FY 1977 Work Scope, (2) specify the FY 1977 cost to EPA of $31,000, and (3) specify the accounting information for fiscal year 1977.

The indicated sections of the subject agreement are amended as follows:

II. SCOPE OF WORK

The detailed scope of work for the current contract, to be partially supported by EPA funds through this IAG, is enclosed with this letter amendment and becomes a part of the IAG.

IV. FUNDS

EPA's fiscal year 1977 share of the cost of the contract is estimated to be $31,000. Accounting information is as follows:

Appropriation No. 687/80108.
Account No. 767733A099.
Document Control No. A00069.
Object Class 25.70.

If this amendment is agreeable to you, please indicate FDA acceptance below and return one signed copy to the Office of Radiation Programs, Attn: Dr. R. J. Augustine (AW–458). A copy of the original IAG is enclosed for your information.

Sincerely yours,

EDWARD F. TUERK,
Acting Assistant Administrator for Air and Waste Management.

THE SURGEON GENERAL OF THE NAVY,
Washington, D.C.

Hon. ADLAI E. STEVENSON,
Hon. WENDELL H. FORD,
Committee on Commerce, Science, and Transportation,
U.S. Senate, Washington, D.C.

DEAR SENATORS STEVENSON AND FORD: I am very happy to provide the enclosed responses to your letter of 20 May 1977 concerning the Senate Committee on Commerce, Science, and Transportation hearings reviewing the current status of radiation research and regulatory programs.

The enclosed material is limited to the activities under the cognizance of the Bureau of Medicine and Surgery including the Navy's Extremely Low Frequency (ELF) program in support of Project SEAFARER.

The total biological/ecological program for Project SEAFARER is sponsored by the Naval Electronics Systems Command. It is supervised by a senior medical officer assigned to the SEAFARER Project Office on an additional duty basis and is thus available for inclusion. Several other Navy organizations and Systems Commands under the Chief of Naval Operations have various related radiation responsibilities particularly for environmental monitoring of field activities and ships. Should this information be required, it is recommended that the Secretary of the Navy or the Chief of Naval Operations be contacted.

The Bureau of Medicine and Surgery has three major responsibilities in the area of radiation. The first is to provide research into the biological effects and any attendant or potential hazard to the health of personnel. The second responsibility is to issue appropriate instructions on exposure standards and to provide for adequate personnel monitoring where needed. Pertinent Navy instructions are enclosed. Finally, it is responsible to be ready and capable for providing medical treatment of radiation injuries.

In the fifties and sixties, the Navy conducted a very active medical research effort in ionizing radiation at the Naval Radiological Defense Laboratory in San Francisco. With its closure in the late sixties, the medical research program in ionizing radiation was phased out.

In 1970, the radiation area was evaluated and decisions were made concerning future directions. It was decided that future medical research requirements for ionizing radiation could be met by the research program being conducted at the Armed Forces Radiobiology Research Institute in Bethesda, Maryland.

In the area of non-ionizing radiation, the Navy had long recognized the potential hazards of electromagnetic radiation (EMR) to other electronic devices, ordnance and fuel, but recognition and emphasis as to what effects EMR had upon personnel had been lacking. In reviewing the current state of the art, it was determined that there were many questions as to the acceptability of, and scientific basis for, the exposure standards. It was determined that the need for medical/biological information concerning the effects of EMR was of sufficient urgency and importance to warrant extraordinary attention and emphasis.

To address this problem, the Chief, Bureau of Medicine and Surgery, with concurrence of the Assistant Secretary of the Navy for Research and Development, issued BUMEDINST 6470.11 establishing an EMR Project Office. The instruction was recently updated as BUMEDINST 6470.11A. The Director of the Project Office provides a centralized point of contact within the Navy for coordination and integration of the Navy's medical research program in all areas of radiation, with particular emphasis on non-ionizing radiation. He also functions as the primary point of contact for liaison outside the Navy. In addition to the medical research program managed by the EMR Project Office, the Office of Naval Research (ONR) sponsors some research in this area. In FY 1977, ONR is sponsoring about $350K of biomedical research in addition to the Medical Department's program.

The two major areas of Navy research have been microwaves and extremely low frequency radiation, which supports Project SEAFARER. For your information, the total FY 1977 research program is summarized on the enclosed Office of Telecommunications Policy resume forms.

The entire Navy EMR program is closely coordinated with the other services through the Tri-Service EMR Panel and with other federal agencies via the "Interagency Side Effects Working Group" of the Office of Telecommunications Policy.

The Navy conducted only a small research program in laser medical hazards from 1970 through 1974. In 1974, the decision was made to discontinue research in this area since both the Army and Air Force had major programs and could carry out the required research in support of the Navy programs more effectively. Presently, research requirements are coordinated with the other services through the Tri-Service Laser Panel. The Naval Medical Research and Development Command has not sponsored any research in the area of ultrasound.

The following is in response to the specific questions asked in your letter (numbers conform with your question numbers).

1. There have been no major changes in the Medical Department's overall responsibilities in the radiation area. But as a result of new legislation and the creation of new agencies, there have been impacts on meeting these responsibilities.

The enactment of PL90-602 which established electronic product emission standards; the enactment of PL99-190, the National Environment Policy Act which requires Environment Impact Statements be prepared to assess proposed actions; the enactment of PL91-596, the Occupational Safety and Health Act which provides for establishment of occupational health standards; Executive Order 11807 of 20 September 1974 which directs federal agencies to be consistent with OSHA standards; the President's Reorganization Plan #3 establishing the Environmental Protection Agency (EPA) are examples of recent federal actions which have had an impact upon the radiation program. They have increased the Medical Department's need to provide liaison with a greater variety of federal agencies, to reissue some instructions to insure consistency with newly established standards, and to allocate some additional resources to insure compliance.

In the non-ionizing radiation research area, two major significant events were the establishment of the Electromagnetic Radiation Management Advisory Council (ERMAC) by the Office of Telecommunications Policy (OTP) and the assumption of a coordinating function for this area by OTP. These two events have resulted in, for the first time, a totally coordinated research program between the federal agencies involved.

Since almost every federal agency utilizes the electromagnetic spectrum in carrying out its basic mission, they each have certain responsibilites to insure that such use is compatible with the total environment. In addition, agencies with regulatory authority must insure that any rules or regulations issued have a clear balance between any risks and benefits.

Because of this multi-agency involvement, ERMAC and OTP have had a profound effect upon the current research program in EMR. The ERMAC program recommendations have provided concrete guidance to all agencies for research in this area. In addition, ERMAC has periodically reviewed each agency's program for scientific content and productivity. Its constructive comments on the Navy's research have been very helpful in improving the overall program.

The coordination effort provided by OTP through its "Side Effects Committee" has greatly increased the awareness of each federal agency to the activity and research of other federal agencies. To our knowledge, this area is the only one in the entire Federal Government where agencies with an active interest in a single area are aware of each other's programs and interact with each other on a day-to-day basis. As a result of this activity, a focal point for EMR research has been established within many agencies, relevant research has been identified and significant efforts have been made in developing cooperative interagency programs.

2. There is little interaction between the Navy Medical Department and state agencies. On occasion, Navy medical personnel have provided briefs to state officials concerning specific Navy systems. There has also been some contact with state agencies concerning specific environment impact statements of Navy systems, e.g., Project SEAFARER. There has not been any confusion concerning responbilities between the various states and the Navy Medical Department.

3. The present federal radiation regulatory programs could be significantly improved if the jurisdiction of each federal agency having regulatory authority was clearly defined. Priority attention should be given to insure that any regulations covering occupational, environmental, or product emissions have a consistent underlying rationale. These standards must also be based upon reliable and adequate research data. In the area of research program management the non-ionizing research program coordinated by OTP (as noted before) is excellent. Contrasted with this program there appears to be far less coordination of the other research areas by the involved federal agencies.

The Medical Department does issue appropriate health instructions based upon the guidelines and standards issued by the federal regulatory activities. In some cases where there are unique naval requirements, the Bureau develops its own regulations, but it is not considered to have wide regulatory responsibilities as the Occupational Safety and Health Administration or the Bureau of Radiological Health. At the present time there are adequate funds requested in outyear budgets for this function. However, there is a funding deficiency within our EMR research program. Based upon a detailed analysis by the EMR project Office, there is a critical need for an additional 1.5 million dollars in FY 1978 for new exposure equipment and facilities. This is a one-time requirement. In addition, there is a continuing requirement to increase the EMR Project Office program funding by 600 thousand dollars per year to more adequately meet the continuing research requirements.

4. The specific proposals for a single radiation agency referred to in your letter are not familiar to the Bureau. At first thought, such a proposal to consolidate all federal radiation activities into one federal agency sounds interesting. But with additional thought and reflection, it is difficult to comprehend. Radiation is a very broad term, so that what is included must be clearly defined. In a broad context of "all radiation activities", this would include all research, technology development, and regulatory activities for such diverse areas as nuclear reactors, radioactive drugs, medical diagnostic and therapeutic x-rays, management of electromagnetic spectrum, allocation of frequencies, and even regulation of 60 Hertz Power Systems.

In one small area of radiation, the Atomic Energy Commission (AEC) was such an all inclusive agency in being responsible for research, development, and regulation of ionizing radiation. The AEC was recently separated into two activities because of fears over possible conflicts of interests. Even then the AEC did not have jurisdiction over all ionizing radiation activities, i.e., the use of medical X-rays.

These are just a few of the many complex issues involved with the broad use the word "radiation". Without a clear and concise definition of what is meant by the term "radiation activity", it is certainly impossible to endorse such a concept.

It is the Medical Department's position that, because of the many facets to the term "radiation" and the use of one or more components of the broad radiation field by many federal agencies in the pursuit of their basic missions, a single federal radiation agency is not practical or desirable.

Sincerely,

W. P. ARENTZEN,
Vice Admiral, Medical Corps, U.S. Navy.

MATRIX SUMMARY

The only records maintained for the research programs are fiscal data. In-house personnel are assigned to work on individual work units by each laboratory commander as the needs arise. Thus personnel positions are not readily identifiable. Therefore, only funding data have been provided for each in-house research area vice number of positions. It should be noted that use of the funds includes civilian salaries, animal costs, and all supplies and equipment utilized for that research program. It does *not* include salaries for military personnel working in the research areas. In the non-research areas, best estimates for man-years and costs have been provided based upon records maintained in the Bureau of Medicine and Surgery.

Since the Navy programs are not alined exactly as described on the enclosed matrices, some arbitrary decisions have been made in the placement of Navy programs under the closest appropriate heading. A short description of the programs included under each heading follows.

1. *Studies to determine human health effects.*—All medical research utilizing animal studies whose goal is to determine or evaluate the biological effects of electromagnetic or ionizing radiation.

2. *Ecological efforts.*—Research which is directed toward evaluating the effects upon plant and animal life *per se* have been included in this area. Some studies involving animals are pure ecological, e.g., bird migration. While other studies apply equally to human health by extrapolating the results to man. In this case, the cost has been listed in the above category.

3. *Agricultural research.*—The Navy has not conducted any studies directed toward agriculture.

4. *Criteria and/or standards development.*—The Bureau of Medicine and surgery issues instructions related to health hazards and exposure standards. These instructions are consistent with federal standards issued by the regulatory agencies. Thus, the time devoted to their development is very minimal. Therefore, no man-years or funds have been listed.

5. *State/federal liaisons.*—The Navy Medical Department does not routinely maintain liaison with state governments in the radiation area. But on occasion medical personnel have interacted with state officials concerning specific Navy systems, e.g., a one-day briefing of state officials on the biomedical aspects of Project SEAFARER. Because of its infrequent nature, time and costs are negligible. In the environmental area the Navy is required to meet all federal, state, and/or local requirements. The interface with state and local authorities is the responsibility of the local Navy activity. It is the Department of Defense policy that all military installations close contact and cooperate fully with the local governments.

There is a continuing interaction and liaison between the Navy and other federal departments and agencies. Many are formal groups such as the "Side Effects Working Group", the "Tri-Service EMR Panel", and a formal Navy-Bureau of Radiological Health agreement for joint funding of some extra-mural research. In addition to interface at the senior managerial level, there is also a great deal of interaction by individual investigators at the laboratory level.

It is impossible to assign a dollar value to this liaison and just as difficult to estimate man-years since no one person devotes the majority of his time to this effort nor are any records kept for this type of activity. An unverifiable estimate of man-years has been made.

6. *Licensing, certification, inspection.*—The Navy does not routinely provide licensing or certification as this is performed by the responsible regulatory agency. Inspections are primarily performed by medical personnel in conducting the personnel monitoring programs. These have all been included in the next item, as man-years are impossible to separate.

7. *Monitoring and/or surveillance.*—Efforts directly related to monitoring personnel in an occupationally exposed environment, e.g., ionizing radiation survey program. The periodic physical examinations of occupational workers is performed by local medical facilities. No records are maintained at the Bureau, thus it is impossible to provide data on this aspect without a complete response from all the local medical facilities.

8. *Medical diagnostic, therapeutic.*—Most all medical facilities, ashore and afloat, have X-ray capabilities for diagnostic purposes. Several major hospitals also have full capabilities for therapeutic treatment with ionizing radiation. In addition, major hospitals provide nuclear medicine services. Many treatment facilities also have ultrasound diagnostic equipment and ultrasound and diathermy treatment capabilities. Personnel and fiscal records maintained by the Bureau of Medicine and Surgery are not structured to identify resources utilized by these line items. Personnel and funding data are impossible to estimate without a comprehensive survey of all Navy medical facilities. Needless to say, there is extensive use of ionizing and non-ionizing radiation within Navy medical facilities.

The Navy has not conducted medical research in the diagnostic and therapeutic uses of ionizing or non-ionizing radiation. Such research does not meet unique Navy needs. Therefore, it is considered to be the responsibility of the National Institutes of Health.

9. *Collection and/or analysis of health data.*—Specific health data or physical examinations collected and evaluated as part of a research program.

10. *Collection and/or analysis of environmental data.*—General environmental surveys of plants, animals, etc. to determine status of environmental conditions.

11. *Other biological or physical effects studies.*—Studies in this category include those investigating fundamental mechanisms or inferaction between EMR and biological systems, dosimetry studies, mathematical modeling, theoretical analysis of tissue absorption of EMR energy and instrument development.

12. *Other studies.*—Includes contract support for management studies, engineering support, literature search and acquisition, and costs of environmental impact statements.

EXTREMELY LOW FREQUENCY PROGRAM IN SUPPORT OF PROJECT SEAFARER

IH=Inhouse funds in thousands.
EM=Extra-mural funds in thousands.
T=Total funds in thousands.
MY=Man-years.

*Estimated man-years of contact with state governments concerning project SEAFARER.

**1976 includes funds for FY 1976 plus the transition quarter.

***In 1977. the contractor assumed responsibility for collecting health data on contract employees at SEAFARER's Wisconsin Test Facility as part of his normal corporate occupational program.

****The biological/ecological area is programmed for $1600K in FY 1978. but the exact program use of funds has not been determined pending the receipt of the National Academy of Sciences' report by the Navy.

EXTREMELY LOW FREQUENCY

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968	IH-0 EM-180 T-180	IH-0 EM-60 T-60								IH-0 EM-237 T-237		
1969	IH-0 EM-123 T-123	IH-0 EM-50 T-50								IH-0 EM-200 T-200		
1970	IH-95 EM-35 T-130	IH-0 EM-15 T-15								IH-0 EM-450 T-450		
1971	IH-200 EM-20 T-220	IH-0 EM-15 T-15								IH-0 EM-440 T-440		
1972	IH-270 EM-145 T-415	IH-0 EM-155 T-155			MY-1.0*					IH-0 EM-483 T-483		
1973	IH-360 EM-80 T-440	IH-0 EM-120 T-120			MY-1.0				IH-25 EM-0 T-25	IH-0 EM-491 T-491		
1974	IH-125 EM-50 T-175	IH-0 EM-68 T-68			MY-1.0				IH-25 EM-0 T-25	IH-0 EM-238 T-238		
1975	IH-185 EM-240 T-524	IH-0 EM-155 T-155			MY-1.0				IH-25 EM-0 T-25	IH-0 EM-150 T-150		
1976**	IH-864 EM-100 T-964	IH-0 EM-40 T-40			MY-1.5				IH-25 EM-0 T-25	IH-0 EM-1995 T-1995		IH-0 EM-156 T-156
1977	IH-799 EM-180 T-979	IH-0 EM-40 T-40			MY-2.0				***	IH-0 EM-360 T-360		IH-0 EM-130 T-130
Est. 1978****					MY-2.0							

In-House (Positions)
Extra-Mural (Funds)
Total Funds
applies to all years

IONIZING RADIATION

applies to all years

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 In-House (Positions)	IH-817 EM-0 T-817						**					
1969 Extra-Mural (Funds) Total Funds	IH-500 EM-0 T-500											
1970	IH-50 EM-0 T-50											
1971	*											
1972							IH-0.2 EH-0 T-0					
1973							IH-0.58 EM-0 T-0					
1974							IH-0.44 EM-0 T-0					
1975							IH-0.59 EM-0 T-0					
1976							IH-0.83 EM-0 T-0					
1977							IH-1.5 EM-0 T-0					
Est. 1978							IH-2.0 EM-0 T-0					

IH=In-house research funds in thousands.
EM=Extra-mural research funds in thousands.
T=Total research funds in thousands.

*Naval Radiological Defense Laboratory closed; medical program terminated.
**No records are available prior to 1972. Surveillance in-house lists man-years.

LASERS

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)							**					
1969 Extra-Mural (Funds) Total Funds												
1970	IH-0 EM-15 T-15											
1971	IH-24 EM-23 T-47											
1972	IH-13 EM-10 T-23						IH-0.03 EM-0 T-0.5					
1973	IH-10 EM-38 T-48						IH-0.07 EM-0 T-1.4					
1974	IH-20 EM-37 T-57						IH-0.09 EM-0 T-0.55					
1975							IH-0.01 EM-0 T-0.64					
1976 *							IH-0.13 EM-0 T-1.4					
1977							IH-0 EM-0 T-0					
Est. 1978							IH-0.12 EM-0 T-2.4					

applies to all years

IH = In-house research funds in thousands.
EM = Extra-mural research funds in thousands.
T = Total funds in thousands.

*1976 includes funds for FY 1976 and Transition Quarter.
**No records available prior to 1972. Surveillance in-house lists man-years.

MICROWAVES

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968	------						**				IH--- EM-22 T-22	
1969	IH-0 EM-100 T-100				MY-0.2 ***						IH--- EM-211 T-211	
1970	IH-447 EM-309 T-756				MY-0.3						IH-80 EM-122 T-202	
1971	IH-165 EM-359 T-524				MY-0.5						IH-130 EM-97 T-227	IH-0 EM-40 T-40
1972	IH-447 EM-512 T-959				MY-0.5		IH-0.16 EM-0 T-2				IH-75 EM-141 T-216	IH-0 EM-75 T-75
1973	IH-484 EM-547 T-1031				MY-2.0		IH-0.09 EM-0 T-0.8				IH-160 EM-190 T-350	IH-0 EM-30 T-30
1974	IH-626 EM-454 T-1080				MY-3.0		IH-0.06 EM-0 T-0.8				IH-166 EM-290 T-456	IH-0 EM-3 T-3
1975	IH-571 EM-596 T-1167				MY-3.0		IH-0.33 EM-0 T-3.9				IH-122 EM-281 T-403	IH-0 EM-68 T-68
1976 *	IH-999 EM-686 T-1685				MY-4.0		IH-0.25 EM-0 T-5.7				IH-130 EM-370 T-500	IH-0 EM-50 T-50
1977	IH-711 EM-616 T-1327				MY-4.0		IH-0.35 EM-0 T-3.7				IH-120 EM-378 T-498	IH-0 EM-57 T-57
Est. 1978	IH-618 EM-690 T-1308				MY-4.0		IH-0.28 EM-0 T-5.6				IH-157 EM-375 T-532	IH-0 EM-60 T-60

In-House (Positions)
Extra-Mural (Funds)
Total Funds
applies to all years

IH = In-house research funds in thousands.
EM = Extra-mural research funds in thousands.
T = Total funds in thousands.
MY = Man-years.

*1976 includes funds for FY 1976 and Transition Quarter.
**Records for monitoring and surveillance not available prior to 1972. In-house is in man-years.
***Estimated man-years for Federal Liaison; no funds are involved.

DEPARTMENT OF THE AIR FORCE,
HEADQUARTERS UNITED STATES AIR FORCE,
Washington, D.C., June 8, 1977.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology, and Space Subcommittee, U.S. Senate, Washington, D.C.

DEAR SENATOR STEVENSON: This is in response to your joint letter with Senator Wendall H. Ford of 20 May 1977 concerning federal radiation research and regulating programs.

The Air Force program information you requested is provided in the attached matrices and narrative descriptions. The answers to the specific questions in your letter touch upon broad policy matters which equally affect all Department of Defense agencies. The Director of Defense Research and Engineering, Department of Defense, has developed a coordinated response which fully represents our position on these questions.

Sincerely,

Lt. Gen. GEORGE E. SCHAFER, *U.S.A.F.*,
Surgeon General.

AIR FORCE RESEARCH AND REGULATORY PROGRAM DATA

1. Two sets of matrices are provided, one for ionizing radiation (Atch. 1) and one for non-ionizing radiofrequency radiation (RFR) (Atch 2). Data entries in each matrix block are coded in numerical order from one to three as follows:

1. Manyears expended, both military and civilian.
2. Extra-mural (contract) dollar costs in thousands.
3. Total dollar costs including extra-mural costs, and direct in-house costs and wages in thousands.

2. Narrative descriptions (Atch 3) are provided for each of the matrices headings and are keyed alphabetically as appendices (A thru L) to the headings starting from left to right, e.g., Appendix A provides a narrative description of information under Heading A, Studies to Determine Human Health Effects.

IONIZING RADIATION

	A	B	C	D	E	F	G	H	I	J	K	L
Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968	1. 83.1 2. 601 3. 2040	No input	No input	0.3 - 5.4	0.35 - 6.3	15.7 - 267	51.5 - 508	No input entries in this area	21.7 - 141	No input	No input	No input
1969	1. 66.1 2. 589 3. 1820			0.3 - 5.4	0.35 - 6.3	15.8 - 268	52.2 - 514	included in F and G	21.7 - 142			
1970	1. 67.1 2. 459 3. 1861			0.3 - 5.4	0.35 - 6.3	15.7 - 268	52.7 - 521		21.7 - 144			
1971	1. 55 2. 275 3. 1365			0.3 - 5.4	0.35 - 6.3	16.2 - 273	51.9 - 517		21.7 - 146			
1972	1. 53 2. 225 3. 1351			0.3 - 5.4	0.35 - 6.3	16.2 - 276	52.7 - 545		21.7 - 149			
1973	1. 54 2. 327 3. 1416			0.3 - 5.4	0.35 - 6.3	15.1 - 254	52.9 - 548		21.7 - 151			
1974	1. 54 2. 280 3. 1368			0.3 - 5.4	0.52 - 9.3	18.5 - 317	53.5 - 557		21.7 - 153			
1975	1. 51 2. 230 3. 1328			0.3 - 5.4	0.52 - 9.3	21 - 417	54.7 - 597		21.7 - 156			
1976	1. 50 2. 250 3. 1308			0.3 - 5.4	0.43 - 7.8	22.1 - 381	53.8 - 577		21.7 - 159			
1977	1. 49.2 2. 245 3. 1229			0.3 - 5.4	0.43 - 7.8	20.7 - 368	54.2 - 598		20.6 - 161			
Est. 1978	1. 50 2. 250 3. 1300			0.3 - 5.4	0.5 - 8	21 - 370	54 - 600		22 - 160			

NON- IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968	1. 6.0 2. 50 3. 161	No input	No input	.1 - 1.8	.35 - 6.3	.5 - 14.6	8.2 - 236	No input	No input	No input	- -	No input
1969	1. 7.5 2. 60 3. 197			.1 - 1.8	.35 - 6.3	.5 - 14.6	8.2 - 236				0.5 - 11	
1970	1. 9.0 2. 65 3. 223			.1 - 1.8	.35 - 6.3	.5 - 14.6	9.2 - 242				1.0 - 27	
1971	1. 10 2. 107 3. 263			.6 - 17.8	.35 - 6.3	.5 - 14.6	10.2 - 246				1.5 - 50	
1972	1. 11 2. 170 3. 299			1.1 - 38.8	.35 - 6.3	.5 - 14.6	10.2 - 246				2.0 - 74	
1973	1. 10.5 2. 246 3. 368			1.1 - 36.8	.35 - 6.3	1.0 - 29.1	44.2 - 330				2.5 - 86	
1974	1. 11 2. 249 3. 412			1.1 - 38.8	.35 - 6.3	1.0 - 29.1	44.2 - 316.				3.0 - 112	
1975	1. 13 2. 245 3. 537			1.1 - 42.8	.35 - 6.3	1.0 - 29.1	44.2 - 312				2.0 - 8.3	
1976	1. 18.4 2. 428 3. 820			1.6 - 67.8	.35 - 6.3	1.0 - 29.1	44.4 - 313				1.1 - 64	
1977	1. 16 2. 500 3. 766			1.6 - 73.8	.35 - 6.3	1.0 - 29.1	44.4 - 340				0.5 - 24	
Est. 1978	1. 16 2. 500 3. 770			1.6 - 74	.4 - 7	1.0 - 29	44 - 315				0.5 - 24	

APPENDIX A—STUDIES TO DETERMINE HUMAN HEALTH EFFECTS

IONIZING RADIATION

Programs are Air Force specific and are designed to define aircrew performance decrements and exposure limits to ionizing radiation predicted to be received during air operations in a nuclear war. This research program on aircrew survivability/vulnerability, is coordinated within the Air Force at the Air Force Weapons Laboratory with the biomedical effects portion the responsibility of the USAF School of Aerospace Medicine (USAFSAM) under the Aerospace Medicine Division (AMD) at Brooks AFB, Texas, Tri-Service coordination has been achieved through the Defense Nuclear Agency (DNA) annual long range planning meetings and DNA Interagency funding of a portion of the Air Force crew vulnerability program. Specific descriptions of programs are given in attachment 1 to this Appendix.

NONIONIZING RADIATION

The early USAF program (1968-72) was primarily structured to evaluate the HF band (3–30 MHz) in support of the Over-the-Horizon Radars (441A and 414L). Surplus transmitters were acquired, fields were mapped, and calibrated by NBS, and primate data confirmed the adequacy of the 10mW/cm^2 safety level for these systems. The early R&D effort was primarily "reactive to developer and user needs; however, in the 1972–74 period, a long range R&D plan was formulated and coordinated with the US Army and Navy in the biomedical TCP. A comprehensive Tri-Service plan was developed in 1974–76 and submitted to ODDR&E. The USAF portion of this plan was largely oriented toward dosimetry, accurate determination of energy distribution and measurement, and appropriate scaling factors for extrapolation of animal data to man. The long range planning identified evolving phased array radar technology as an area requiring additional bioeffects data. The USAF has published a Required Operational Capability on this topic and initiated acquisition of a peak pulse power simulator to acquire essential effects data to support these new development efforts (PAVE PAWS, COBRA DANE, COBRA Judy, etc). The USAF program is closely coordinated with the other services and the OTP–ERMAC. Attachments 2 and 3 are copies of the FY 76 research summaries and project resumes provided to OTP.

ATTACHMENT 1 TO APPENDIX A—IONIZING RADIATION PROGRAM DESCRIPTION

Fiscal year 1968—Performance studies on rhesus monkeys were initiated using refined behavioral methods to produce data on reaction time changes as a function of ionizing radiation. The subjects were taught to perform tasks under highly motivating conditions so that high dose pulsed radiation effects could be assessed for nuclear weapon *"near miss"* threats.

Fiscal year 1969—High dose rate pulsed reactor studies were conducted to produce performance decrement curves for incapacitating and instantly debilitating aircrews in a simulated nuclear environment. Nausea, vomiting, blood pressure changes, etc., were measured.

Fiscal year 1970—Several animal species were studied to make extrapolations from among the primates (e.g., baboons, rhesus, cynomolgus, and squirrel monkeys) with respect to radiation response. The data provided confidence in certain extrapolation factors to human performance.

Fiscal year 1971—Primate Equilibrium Platform (PEP), displaying pitch and roll, were refined to allow collection of analog data for later development and application of linear mathematical models of aircrew performance.

Fiscal year 1972—Cognitive tasks vs simple work variables were studied as a function of ionizing radiation. The role of the decision-making processes and subsequent degradation of faculties is relevant to nuclear weapons delivery systems. These studies formed the basis of the math model on crew vulnerability as applied to the Space Shuttle and the B–52.

Fiscal year 1973—Studies were conducted at the AFRRI and Texas A&M reactors to establish a comparative data base for neutron/gamma ratios as effectiveness factors in disrupting aircrew performance. Vomiting studies were compared with emetic episodes among nuclear accident victims, and a nomogram developed as a guide to commanders.

Fiscal year 1974—Performance decrement curves for single pulses of ionizing radiation were refined using rhesus monkeys highly trained to perform precise psychomotor tasks which are similar but simplified versions of aircraft tasks. Tables of "sure safe", probable "mission completion", "probable kill", and "sure kill" were developed by dose (rad) and time (hours).

Fiscal year 1975—A refined estimation algorithm was perfected to quantify percent aircraft losses due to aircrew duty performance failures resulting from ionizing radiation and flashblindness. Such estimations represented "first look" quick responses to this very real HQ SAC interest item. This model led to later more sophisticated models of performance decrements.

Fiscal year 1976—Experiments to define the nausea and vomiting responses which can be expected to result from nuclear weapons irradiation have been conducted under a variety of likely exposure conditions. Statistical curves, ED_{50}—effective dose in fifty percent of the crews, have been produced to clarify this expected radiation threat to job performance.

Work was initiated to identify anti-nausea/vomiting drugs which aircrew members could use without adverse side effects (e.g., drowsiness, fatigue, etc). Crew hardening was the goal of this effort.

Work continued in mathematical models.

Fiscal year 1977—The current research program simulates tactical nuclear warfare in advanced bomber and fighter missions. Laboratory replications of ground based aircraft simulators located in radiation exposure facilities are used to evaluate high skill level performance decrements in rhesus monkeys. Missions of 1-hour; 10-hours; 12-hours and 72 hours have been performed with specific threat scenarios operating against AF weapons systems.

SUMMARY OF USAF RADIOFREQUENCY RADIATION BIOEFFECTS RESEARCH ACTIVITIES 1976—INPUT TO OTP/ERMAC

The USAF radiofrequency radiation (RFR) research program is comprised of contractual and in-house efforts in a ratio of about 65 percent and 35 percent respectively. It includes studies of: (1) RFR energy transfer, distribution and measurement, (2) effects on the central nervous system, (3) effect on immune systems, (4) cellular level effects, (5) medical device interference, (6) the effect of fractionated (long term) exposures, (7) effect of combined stress, and (8) the effects on behavior. More recent efforts are directed to the study of the specific biological consequences of man's exposure to a variety of pulsed RFR fields relative to continuous wave exposure.

As a part of the Tri-Service priority one effort (Energy Distribution and Measurement), the Air Force has undertaken a multi-year program to develop an RFR Dosimetry Handbook. The first edition of the handbook was prepared under Air Force contract by the University of Utah and published as USAF School of Aerospace Medicine Technical Report 76–35 in Sep 1976. More than 300 copies have been distributed to researchers in the United States and Europe. Initial response concerning the acceptance and use of this handbook is very favorable. Many of the calculated curves are being empirically validated. A follow-on program will seek out suggested improvements in the handbook's content and use. Furthermore, additional empirical data is being actively solicited for inclusion in the next edition (scheduled about Oct 77). In the final analysis, this effort should provide the necessary link between biological effects observed in irradiated animals and corresponding effects which might occur in man.

The Air Force approach to RF bioeffects studies is in direct support of Systems Development and relates observed response to thermally induced events and to specific absorbed power whether local, regional, or whole body. Energy transfer thresholds for such biological response and the relative efficiency of pulsed versus continuous wave exposures as well as the influence of duration of exposure, i.e., acute or chronic should lead to conceptual models from which any combination of threat modalities can be predicted. This approach could obviate the need for long and arduous research studies at every frequency level of interest and for each new mode of delivery.

The fact that RF radiation induced biological effects are frequency dependent suggests that safety criteria could best be promulgated using a frequency dependent approach. In support of this philosophy, the Air Force developed and published a new regulation in Nov 75., viz, AFR 161–42, Radiofrequency Radiation Health Hazards control. It incorporates, as a conservative first step, a slightly higher frequency dependent exposure level for the 10KHz to 10MHz portion of the RF spectrum, where no previous standard existed. It remains consistent with the OSHA regulation which covers the frequency range 10 MHz to 100 GHz. This new safety standard which defines a complete RFR hazards control program has been accepted throughout the Air Force and has been implemented by all major commands, since it provides detailed guidance on the application of PELs (permissible exposure limits) across the frequency range of AF RF emitters.

Research studies in support of 10–30 MHz RFR emitters (principally the OTH–B radar) were essentially completed this past year. Power absorption studies were completed for the 10–50 MHz frequency band and compared with theoretical calculations. These data have been published on monkeys, prolate spheroid and ellipsoid models. Primate temperature profiles, as a function of incident power densities and time, were completed for three HF band frequencies (15–20, 26 MHz). Power densities ranged from 500 to 1500 mW/cm^2 and exposure times from 0.5 to 6 hours. The previous studies on the effects of HF band radiation on rodent growth and development by SAM and its contractors were reevaluated and documented in SAM–TR–75–51. Air Force program interests are now directed to phased array radar systems using RFR fields in the frequency range 0.4–10 GHz.

Air Force contractual efforts in support of the Tri-Service ocular effects program resulted in the development of a system for noninvasive optical evaluation of RFR induced eye abnormalities. A follow-on contract was awarded to conduct bioeffects studies to evaluate the utility of the completed system. Pending successful validation, this new research tool may be applied to objectively quantitate possible effects of RFR induced eye injury in a series of experiments ranging from acute to long term exposures. It will also provide a permanent record for comparative purposes.

In order to study mechanisms of injury and perhaps reduce the use of animals a specialized exposure system for irradiating cell cultures to broadband RF fields under controlled field and temperature conditions was developed under AF contract with the University of Washington. The system produces a quite uniform electric field strength up to 10,000 V/m (over a frequency range 0–1000 MHz) for a 5 mm sample of culture medium. Preliminary experimental results have been reported. Additional research is in progress.

Microwave inactivation techniques sponsored/developed by the Air Force were used in four distinct and separate studies of RF radiation induced CNS effects. Mice were exposed to 19 MHz using a "near-field" radiation simulator to determine if HF band radiation alters the whole brain level of: (1) serotonin of its metabolite 5-hydroxyindole acetic acid; and/or (2) norepinephrine. Other studies were completed for rates exposed to 1600 MHz fields. Additionally, metal ion concentrations in specific areas of the rat brain were evaluated after 1600 MHz exposures.

A six-port vector voltmeter developed by the National Bureau of Standards under Tri-Service Precision Electromagnetic and Air Force funding and sponsorship has been completed and is in operation at the USAF School of Aerospace Medicine. This instrument is capable of measuring voltage ratio and phrase angle between any two given signals in the 500 MHz to 12 GHz frequency range. Applications of the system include measurement of coupling ratio for high power couplers, measurement of antenna transmittance and reflectance, and measurement of RF field changes induced by insertion of biological systems into an RF field. The system is controlled by an HP model 9830A and has a unique calibration capability.

Recent reports in the literature have indicated changes in the permeability of the blood-brain barrier after exposure to microwaves. Because of the serious safety implications of these reports attempts were made to replicate one of the investigations. In the reported study, 1200 MHz radiation pulsed at a low peak power density (2 mW/cm^2) was reported to increase the permeability of the blood-brain barrier to sodium fluorescein.

In the USAFSAM replication, fluorescence due to sodium fluorescein in the brain substance of irradiated rats was not observed at the peak power reported in the original investigation. The study was extended to include chemical assay of sodium fluorescein in various areas of the brain. At a peak power of 2 mW/cm^2 no increase in the brain concentration of sodium fluorescein was noted. However, at a peak power of 75 mW/cm^2 (37.5 mW/cm^2 average) the fluorescein content was significantly increased as compared to control. At this higher peak power level brain temperature was increased about 4°C. Further research is being carried out to establish a threshold for the increased fluorescein content. Additional studies will be initiated using radiolabeled compounds that do not normally cross the blood-brain barrier. It is strongly recommended that laboratories make a maximum effort to participate in replication of all important research findings.

A series of experiments was conducted to investigate the effects of radiofrequency radiation (RFR) heating on cell-mediated immune defense mechanisms. RFR heating effects, as determined by inflammation and/or the number of peripheral blood and spleen lymphocytes, were followed in rodents exposed to 26 MHz radiation (3° C increase in core temporature), 5 MHz (no measurable increase), and warm-air treatment (3° C increase). RFR heating (26 MHz) decreased SRBC-induced inflammatory footpad swelling by 45% over that observed in warm-air or sham control animals. The suppression of inflammatory response was accompanied by a well-defined, transient four-fold lymphopenia and neutrophilia maximal at 3 hours post-exposure. Normal blood lymphocyte and neutrophil levels were reestablished by 92 hours post-exposure. Triple exposure to 26 MHz radiation at 3-hour intervals achieved a marked, but transient lymphopenia and neutrophilia sustained over a 12-hour period; all animals reverted to normal level by 92 hours after the final exposure. Time course of this lymphocyte response closely follows glucocorticoid-induced lymphopenia and suggests that RFR heating is perceived as a simple stress phenomena accompanied by steroid release. In addition, percentage of T-lymphocytes in the spleens of RFR heated mice (26 MHz) was two-fold greater than that observed in 5 MHz, warm-air, or sham treated animals. That RFR heating induced an arrest in T-cell splenic traffic resulting in apparent pooling of T-lymphocytes in the spleen, in addition to suppression of inflammatory response and lymphopeneia, suggests that cell-mediated immunocompetence may be altered in these animals.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☒ New ☐ Revised
☐ Proposed ☐ Completed
☐ Continued ☐ Terminated

1. Title:
Development of a Phased Array Radiation Simulator
(77570155)

3. Dept./Agency:
DOD/USAF

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:

a. Principal Investigator:

7. Start Date: 0577

8. Estimated Completion Date: 0778

9. Frequency(ies): 200-600 MHz

10. Exposure Range: 0.01-100 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	0.5	15K
Current:	1.0	105K
CFY + 1:	1.0	150K
CFY + 2:	2.0	180K

Project Summary: 12. Objective, 13. Approach

12. Objective: To develop a laboratory phased array emission simulator large enough to expose nonhuman primates. The completed system will be used to quantitate the biological consequences of man's exposure to unique pulsed radiation fields which emanate from specialized Air Force radar/surveillance systems.

13. Approach: Technical approach is pending receipt of proposals.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☒ New ☐ Revised
☐ Proposed ☐ Completed
☐ Continued ☐ Terminated

1. Title:
RFR Effects on Immune Systems (77570154)

3. Dept./Agency:
DOD/USAF

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
R. P. Liburdy

7. Start Date: 0176

8. Estimated Completion Date: 1278

9. Frequency(ies): 10-10,000 MHz

10. Exposure Range: 0.1-100 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	2	60K
Current:	2	60K
CFY + 1:	3	90K
CFY + 2:	4	220 K

Project Summary: 12. Objective, 13. Approach

12. Objective: Investigate the effects of electromagnetic radiation (EMR) stress on immune systems. Specifically to determine the magnitude and direction, cause(s) and thresholds of EMR induced changes in immune responsivity. Also to establish nonputative thresholds for frequency and power dependency of continuous and pulsed wave EMR stress on immune function.

13. Approach: Quantitate, initially, RF induced changes in the ability of test animals to mount a viable *in vivo* cell-mediated immune response-cutaneous delayed hypersensitivity (DTH), to antigenic challenge. Subsequently to delineate through *in vitro* techniques effects of EMR stress on specific cell-mediated effector mechanisms operating in DTH.

14. Progress: Three strains of mice, C56Bl/6, CD-1, and B6D2F1, have been successfully sensitized to mycobacterium H37Ra and to the protein ovalbumin; subsequently vigorous delayed hypersensitivity reactions (as measured by footpad enlargement) were elicited to characterize normal responses in mice in preparation for RF exposure experiments. Studies of RF treated mice (26 MHz, 2000 mW/cm^2, causing a 2.5° C increase in animal rectal temperature) revealed a time-dependent inversion in the relative number of circulating segmented polymorphonuclear leukocytes (PMN) and lymphocytes (L): preexposure, levels within 24 hours. In addition, total leukocyte cell number was depressed at 6 hour postexposure by 25±4% (3564±104 versus 4760±150 cells/cc) over normal control values: this leukocytopenia was transient and normal cell count was observed 12 days after exposures. The above results were presented at the 1976 NRC/URSI meeting in Amherst MA, 11-15 Oct 76 (FY77).

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☒ New ☐ Revised
☐ Proposed ☐ Completed
☐ Continued ☐ Terminated

1. Title:
Development of a Phased Array Radiation Simulator (77570155)

3. Dept./Agency:
DOD/USAF

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:

a. Principal Investigator:

7. Start Date: 0577

8. Estimated Completion Date: 0778

9. Frequency(ies): 200-600 MHz

10. Exposure Range: 0.01-100 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	0.5	15K
Current:	1.0	105K
CFY + 1:	1.0	150K
CFY + 2:	2.0	180K

Project Summary: 12. Objective, 13. Approach

12. Objective: To develop a laboratory phased array emission simulator large enough to expose nonhuman primates. The completed system will be used to quantitate the biological consequences of man's exposure to unique pulsed radiation fields which emanate from specialized Air Force radar/surveillance systems.

13. Approach: Technical approach is pending receipt of proposals.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☒ New ☐ Revised
☐ Proposed ☐ Complete
☐ Continued ☐ Terminat

1. Title:
Effects of Multiple RFR Exposures (77570156)

3. Dept./Agency:
DOD/USAF

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
J. H. Krupp

7. Start Date: 0976

8. Estimated Completion Date: 0978

9. Frequency(ies): 10-10,000 MHz

10. Exposure Range: 0.1-100 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	2	70K
Current:	3	80K
CFY + 1:	3	100K
CFY + 2:	4	120K

Project Summary: 12. Objective; 13. Approach

12. Objective: Reports have appeared with increasing frequency which would indicate microwave exposure effects upon various components of the hematopoetic system, particularly the small lymphocyte. The frequencies and power levels used vary from study t study, but in general encompass areas which represent portions of the spectrum which include existing or planned Air Force systems. This study will attempt to define an RF effect on humoral antibody production, which, if it exists, would be of practical significance as far as the ability of exposed personnel to withstand infection and to develop effective immunity in response to the challenges in the environment.

13. Approach: Hybrid inbred mice will be exposed for prolonged periods (up to six wee to RF radiation at frequencies and power levels which are scaled to represent equivalent human exposure. Following exposure, an antigenic challenge will be made, and the response assayed by measuring the presence of splenic plaque forming cells. Where R effects can be detected, further study will try to define threshold levels, thermal vs non thermal characteristics, and relative efficiency for production of effects from CW or pulsed application over extended periods of time.

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BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
Laser Eye Measurement and Evaluation System (77570153)

3. Dept./Agency:
DOD/USAF AF-14

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
University of Washington
Seattle, Washington

a. Principal Investigator:
A. P. Bruckner

7. Start Date: 0775

8. Estimated Completion Date: 0577

9. Frequency(ies): N/A

10. Exposure Range: N/A

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	0.5	90K
Current:	1.0	80K
CFY + 1:	0.0	0
CFY + 2:	0.0	0

Project Summary: 12. Objective, 13. Approach

12. Objective: Assessment of suspected or actual eye injury resulting from radiofrequency (RF) radiation exposure depends largely on subjective evaluations. The purpose of this project task is to develop a system to quantitate eye abnormalities for RF radiation personnel hazard assessment; specifically to conduct research and development resulting in a portable device (s) capable of both holographic recording and short pulse scattering measurements in the eye. The device is required to quantitate and study radiofrequency radiation-induced eye opacities.

13. Approach: Previous research conducted under a memorandum of agreement with the U.S. National Bureau of Standards and under AF contract with the University of Washington resulted in the development of two promising techniques for noninvasive optical evaluation of RF-induced cataracts in the eye in vivo. The first uses short pulse laser range-gating and scattering measurements to determine the thicknesses of ocular layers and the second records holographically the 3-dimensional internal structure of the eye including microcataracts. These techniques will be incorporated into a system which can be used to quantitate eye changes and produce permanent records of such changes.

14. Progress: Construction of system has been well detailed and assembly of final system has begun. Problems associated with holographic phase coherence were overcome by proper laser cavity loading. Coherence length is approximately 3 cm. Adaptation of fiber optic pickup to range-gated laser pulses demonstrated very good fit to a Mie scattering curve with particle sizes down to 5 μ or less. Completion of Vidicon imaging of Kerr cell range-gate was accomplished, giving range resolution of 1 mm or less without treatment of raw data. Demonstration of particle size distribution in microwave cataracts was accomplished in July 1976.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
Radiofrequency Electromagnetic Environment Simulation and Measurement (77570143)

3. Dept./Agency:
DOD/USAF AF-16

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
S. J. Allen

7. Start Date: 05 74

8. Estimated Completion Date: 0978

9. Frequency(ies): 10MHz-10GHz

10. Exposure Range: 0.01-200 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	4	195K
Current:	4	180K
CFY + 1:	4	200K
CFY + 2:	4	210K

Project Summary: 12. Objective, 13. Approach

12. Objective: The objectives of this work unit are to develop equipment and methodology and to perform the experiments necessary to define radiofrequency (RF) energy transfer to animals and man. The results of these experiments will continue to provide the basis for modifying the personnel exposure criteria for Air Force RF operations.

13. Approach: Instrumentation will be developed to monitor incident fields and absorbed power for biological systems exposed to RF fields in the range of operational AF systems, namely 10 MHz to 10 GHz. Present power absorption techniques are usable from 10 to 50 MHz. Methodology will be developed to measure power absoprtion in the 50 MHz to 10 GHz frequency range. Modeling of animals will continue until a suitable model is found and this model will be used to perform the theoretical analysis necessary to predict power absorption over the frequency range of concern.

14. Progress: Differential power measurements were completed for 20 ellipsoid phantoms, designed to represent the sitting rhesus monkey, and for 20 live monkeys exposed to 10, 20, 30, 40 and 50 MHz RF fields. The phantoms were filled with saline solutions with conductivities of .054, .245, .36, .54 and .64 mho/m. Phantoms and monkeys were measured for six orientations. A new read-out technique was devised using an HP 9830A programmed to read the input, reflected and output power and compute differential power. This technique improved the accuracy of measurement as well as reducing the time required for this set of measurements by a factor of three. Comparison of the power absorbed by the live monkeys was within ± 10% of previous tests.

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BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
Biological Effects of AF RF Transmitter Fields (77570145)

3. Dept./Agency:
DOD/USAF AF-18

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
J. W. Frazer

7. Start Date: 0774

8. Estimated Completion Date: 0878

9. Frequency(ies): 10 MHz-10 GHz

10. Exposure Range: 0.01-1000 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	3	90K
Current:	3	90K
CFY + 1:	2	70K
CFY + 2:	2	70K

Project Summary: 12. Objective, 13. Approach

12. Objective: The setting of safety standards for electromagnetic radiation (EMR) for AF personnel must rest on a foundation of known bioeffects of this type of radiation. The objective of this effort is to investigate radiofrequency (RF) field effects in biophysical model systems. The information gathered will allow the adjustment of exposure criteria for AF personnel working in unique RF radiation environments.

13. Approach: Field modulation effects, including pulsed fields, on a variety of central nervous system (CNS) ionic and chemical distributions will be examined. The effects of EMR fields on solvent transport processes in tissue and polarization processes in macromolecules will also be investigated. An attempt will be made to relate alterations in the trace metal content in various areas of the rat CNS with frequency, power density and thermal stress, and to extrapolate these findings to an expected effect on AF personnel operating in EMR environments.

14. Progress: Trace metal determinations in rat brains are continuing. Current effort nearing completion, utilizes exposure levels calculated not to produce a detectable CNS temperature rise in an attempt to determine an RF exposure threshold for changes in divalent metal ion metabolism. Studies have been completed in which core temperature rise as a function of frequency and power was observed in monkeys exposed for 180 minutes to HF band frequencies. See SAM-TR-76-20 and subsequent report in press.

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EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☐ Continued ☐ Terminated

1. Title:
RFR Interference of Medical Prosthetic Devices (77570146)

3. Dept./Agency:
DOD/USAF AF-1

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
J. C. Mitchell

7. Start Date: 0574

8. Estimated Completion Date: 0678

9. Frequency(ies): 10 kHz-30 GHz

10. Exposure Range: 1-3000 rms V/m

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	2	60K
Current:	2	60K
CFY + 1:	2	60K
CFY + 2:	2	60K

Project Summary: 12. Objective, 13. Approach

12. Objective: To establish a biomedical data base on the interaction of Air Force radiofrequency (RF) radiation emitters and medical prosthetic devices. To maintain a state-of-the-art technology watch on cardiac pacemaker interference. Assess manufacturers' progress in developing pacemakers to operate properly in pulsed RF fields of 200 rms volts per meter. Apply data to operational situations in accordance with AFR 161-42.

13. Approach: New state-of-technology pacemakers will be accepted on loan from device manufacturers and evaluated under a variety of RF emission sources in the USAFSAM laboratory. Sources will include radiofrequencies between 10-500 MHz. Field tests will also be conducted using an HF band transmission system at AVA NY in support of the CONUS OTH PO. Additional field tests will be conducted in support of specific operational problems as provided by AFR 161-42.

14. Progress: Cardiac pacemaker interference data were completed for radiofrequencies of 450, 1600, and 3200 MHz. These results along with summaries of expected effects from several types of radar and other special AF emitters were published in SAM-TR-76-4, "The biological significance of radiofrequency radiation emission on cardiac pacemaker performance," Jan 76. Pacemaker risks criteria were provided HQ USAFE/SG, USAF Hosp Wiesbaden/SGPM, ESD/OCN, and USAF Hosp Lindsey AS GE/SGPM for a series of operational RF emitters. A series of new generation cardiac pacemakers was evaluated under both free-field and simulated implant conditions for radiofrequencies of 250, 350, and 450 MHz. Potential susceptibility levels in rms volts per meter were established for pulse widths of 10 μsec, 1 msec, and 20 msec at 5 and 10 pulses per second. A summary report is in preparation. These data will be provided to the USAF/SG. Consultations concerning EMI risks criteria were provided for the AN/MST-T1, AN/MPN-13, AN/GPS-10, AN/FPS-7, AN/FPS-90, and to other operational systems as requested.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
RFR Effects on Biochemical Systems in the CNS (77570148)

3. Dept./Agency:
DOD/USAF AF-20

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:

USAFSAM/RAP
Brooks AFB TX 78235

a. Principal Investigator:
J. H. Merritt

7. Start Date: 0974

8. Estimated Completion Date: 0978

9. Frequency(ies): 10 MHz-10 GHz

10. Exposure Range: 1-100 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	3	90K
Current:	4	120K
CFY + 1:	4.5	135K
CFY + 2:	5.0	150K

Project Summary: 12. Objective, 13. Approach

12. Objective: The Department of Defense Triservice electromagnetic radiation (EMR) bioeffects research program describes the central nervous system (CNS) as the "singularly most important area where there is evidence that EMR interacts with biological systems." The objective of this effort is to quantitate the radiofrequency (RF) EMR effects on biochemical events subserving nerve transmission in the CNS. The information obtained will be applied to establish more appropriate safety standards for personnel working in close proximity to AF RF emitters.

13. Approach: The effects of RF radiation on the CNS, specifically on a specialized function of the neuron, namely synaptic transmission will be studied. It is probably true to say that every cell in the brain is connected, directly or indirectly, to every other cell by chemical switching systems (synaptic transmission). This effort will attempt to quantify changes produced by RF energy in these chemical systems, determine thresholds for frequency and power density, and interpret these changes in terms of the expected effect on man in AF operational environments.

14. Progress: Temperature profiles for core and brain of rats exposed to 1600 MHz radiation have been obtained. Both brain and core temperature increases are related to the orientation of the animals' long axis in the radiation field, i.e., when the long axis of the rat is parallel to the electric component, the rectal temperature was greater than when the animals' long axis was oriented to the magnetic component. Neurochemical studies show that the neurotransmitters norepinephrine and dopamine are decreased in the hypothalamus of animals whose brain temperatures had been elevated above 5° C by the radiation. An apparent increase in the rate of biosynthesis of the neurotransmitter serotonin, possibly as a result of the increase in temperature of the tissue in the midbrain was noted.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
Comparison of Theoretical and Experimental Absorption of RF Power (77570152)

3. Dept./Agency:
DOD/USAF AF-21

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
University of Utah
Salt Lake City, Utah

a. Principal Investigator:
C. C. Johnson/C. H. Durney

7. Start Date: 1174

8. Estimated Completion Date: 0578

9. Frequency(ies): 10 kHz-10 GHz

10. Exposure Range: 1-100 mW/cm^2 equivalent man exposures

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	0.5	115K
Current:	1.0	130K
CFY + 1:	1.5	150 K
CFY + 2:	1.0	190 K

Project Summary: 12. Objective, 13. Approach

12. Objective: The highest priority task in the DOD triservice electromagnetic radiation (EMR) bioeffects research program is to develop better methodology for quantitating EMR energy distribution and measurement. Methods and data are critically needed to extrapolate (via appropriate scaling factors) animal data to man and thus to establish more realistic personnel safety exposure guidelines for AF operations. The specific objectives of this study are (1) to define adequate models, (2) to extend theoretical radiofrequency (RF) power absorption data to assess consequences of man's exposure to 10 kHz to 10 GHz RF radiation fields, and (3) to develop methods, accounting for size and orientation effects, to extrapolate animal exposures to equivalent human exposures.

13. Approach: Twenty phantoms (models) will be constructed to best represent 3.5 kg monkeys. Absorbed power per kg will be calculated utilizing this monkey model for exposures in free space, near field and on a ground plane. Experiments will be conducted to measure power absorbed in the phantom and in actual monkeys for six exposure orientations. The best model for man, monkey, rat and mouse will be developed and calculations performed to determine power density to which these animals should be exposed to produce the same average absorbed power as man when exposed to 10 mW/cm^2 at the same frequency. The exposure frequency for animals subjected to the same power density as man to accomplish equivalent average power absorption will also be calculated. These data will be used to compile an RF Dosimetry Handbook for use in selecting appropriate exposure parameters (frequency and power density) for animal studies to simulate bioeffects in man. Power absorption calculations for man and animals will be extended using wave solution, numerical techniques, or other applicable methods.

Title: Comparison of Theoretical and Experimental Absorption of RF Power (77570152)

14. Progress: Twenty ellipsoid phantoms averaging 3.4 kg were constructed and shipped to the USAF School of Aerospace Medicine. These phantoms were 40 cm in length and the b/c ratio was 1.5. A new molding technique produced a seamless phantom. The radiofrequency radiation handbook was completed and published as SAM-TR-76-35. This document (first edition) provides predictions of specific absorbed power for 14 animal species to aid experimenters in evaluating experimental results and equating such results to equivalent human exposures. About 200 copies were distributed at the 1976 IEEE/URSI meeting. An annual update is planned.

OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Date: 22 October 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title:
Measurement of Power Absorption at Resonant & Nonresonant Frequencies (77570149)

3. Dept./Agency:
DOD/USAF AF-22

4. Funding Component: AFSC/AMD

a. Jointly Funded With:

5. Program Contact: Maj David Beatty
a. Title: Directorate of Dev & Acq
Sci & Tech Div.
b. Phone Number: 202-695-0247
Autovon 225-0247

6. Performing Organization and Address:
University of Washington
Seattle, Washington

a. Principal Investigator:
A. W. Guy

7. Start Date: 1174

8. Estimated Completion Date: 0877

9. Frequency(ies): 20-10,000 MHz

10. Exposure Range: 1-1500 mW/cm^2

11. Resources:

Year	a. Manyears	b. Funds
CFY-1:	0.5	115K
Current:	1.0	145K
CFY + 1:	1.0	160K
CFY + 2:	1.0	185K

Project Summary: 12. Objective, 13. Approach

12. Objective: Extend current energy distribution and measurement methodology using thermographic techniques to more accurately assess RF power deposition in scaled models of man. Determine the thermal load and RF fields in tissue which produce such loads, and determine the rate at which the tissue thermal loads are dissipated. Measure some of the bio-responses to such insults in the frequency range 20 MHz-10 GHz.

13. Approach: Scale models of man will be exposed to 720-980 MHz plane wave fields to simulate the exposure of a full scale man to the high end of the HF band through the UHF band frequency range. Power absorption patterns will be obtained for animals exposed to 0.143, 7.50, 9.14, 2.450, 3.3, and 9.0 GHz at the University of Washington and 0.45, 1.3, 1.6, and 6.0 GHz at SAM. Heat flux equations for locally deposited thermal loads will be developed. Cell culture studies will be initiated.

Continued ....

Title: Measurement of Power Absorption at Resonant & Nonresonant Frequencies (77570149)

14. Progress: An exposure system has been developed for exposing cell cultures to broadband electromagnetic fields under controlled field and temperature conditions. This system can produce a reasonably uniform electric field strength up to 100 V/cm in a 5mm sample of culture medium with system input powers up to 600 W over a frequency range 0-1000 MHz. Temperature control and measurement can be achieved at frequencies up to 100 MHz by the dependence of feedline impedance on culture medium temperature. Steady-state temperatures below 37° C can be maintained with CW exposure of the cultures at field strengths in excess of 25 V/cm. In preparation for in-vitro exposures of cultured primate lymphocytes, preliminary determination of the requisite biological parameters were established and results from initial lymphocyte exposures were documented. A statistically valid (p less than 0. 01, Chi square test) inhibition of cell division was found on exposure of lymphocytes to fields of 5 volts cm^{-1} under very carefully thermostated conditions with gas atmosphere controlled and with simultaneous controls run in normal culture vessels, or in the radiator in the absence of power. Exposures were at 20 MHz. These correspond to fields of several hundred volts/meter external to an experimental animal or man.

APPENDIX B

NO COMMENTS

APPENDIX C

NO COMMENTS

APPENDIX D—CRITERIA AND/OR STANDARDS DEVELOPMENT—IONIZING AND NON-IONIZING RADIATION

Provided under this heading are resources expended by the Air Force in publishing required implementing directives to place the requirement of newly enacted laws, executive orders and federal guidelines into the Air Force management system. In order to insure understanding and compliance with a given law, it is necessary to assign responsibilities and provide mechanisms for accomplishing the specific requirements of the law within the Air Force organizational framework.

When federal guidance has not been promulgated, but a need exists within the Air Force, criteria or standards are developed based on national consensus standards or Air Force conducted/sponsored research on the particular subject area. These resource expenditures are also included under this heading.

Specifically, in 1971–72, the AMD/USAFSAM conducted necessary studies and formulated human electromagnetic pulse (EMP) safety criteria to support EMP tests of the Minute Man II weapon system. These criteria were reviewed and updated in 1974 and appropriate material was provided to the Office of Standards OSHA–DOL. The work identified during 74–77 involved HF band data analysis and the publication of AFR 161–42 RFR Health Hazards Control.

APPENDIX E—STATE/FEDERAL LIAISON—IONIZING AND NON-IONIZING RADIATION

Included in this heading are resources expended maintaining liaison with federal agencies. Liaison is maintained with states at the local installation level in the areas of radiation health effects out of professional courtesy. Liaison with other federal agencies is maintained through Air Force participation in federal/interagency working groups and committees; through participation in interagency programs such as the BRH's Nation-wide Evaluation of X-Ray Trends Program, and through the formal mechanisms of replies to published notices for information or rulemaking in the Federal Register.

APPENDIX F—LICENSING AND INSPECTION

IONIZING RADIATION (LICENSING AND CERTIFICATION)

The Air Force Medical Materiel Field Office (AFMMFO) manages a program for acceptance testing maintenance and periodic inspection of diagnostic x-ray systems. The AFMMFO was officially organized in 1957 and has had primary responsibility for the program since that date. As a part of its mission, AFMMFO promulgates internal Air Force directives concerned with the calibration, maintenance, and acceptance of diagnostic x-ray systems and other medical devices. The implementing regulations issued by the Food and Drug Administration in accordance with PL 90–602, required changes in maintenance, calibration, and acceptance procedures. Procedural changes which were adopted during 1975 were made to insure that equipment system purchased and maintained by the USAF remained in compliance with the intent of PL 90–602. This action resulted in an initial capital investment for specialized test equipment of an estimated $58,000 and a 12% increase in workload associated with the maintenance, calibration, and acceptance of diagnostic x-ray systems. This workload is spread over some 116 different locations throughout the world and equates to an estimated 6 manyears. In addition, an estimated 1 manyear is used in central program management and training of Air Force technicians.

Positive Air Force control over the use of all radioactive materials in the Air Force has been assured through the establishment of a Radioisotope Committee. This committee acts as the single point of Air Force contact with the US Nuclear Regulator Commission for radioisotope licensing matters, and oversees the use of radioactive items maintained on the Air Force license.

IONIZING AND NONIONIZING RADIATION (INSPECTION)

Compliance with Air Force directives and federal law Air Force-wide is assured through the inspection activities of the Air Force Inspector General (IG). The Air Force IG acts as an internal inspection and audit agency for the Air Force and identifies deficiencies or noncompliance with Air Force directives or federal laws to responsible commanders throughout the Air Force chain of command. Through Air Force-wide inspections of installations both local deficiencies and Air Force-wide program weaknesses are identified for corrective action.

APPENDIX G—MONITORING AND/OR SURVEILLANCE

IONIZING AND NONIONIZING RADIATION

As part of the overall Air Force Occupational Health Program, routine field surveys of radiation sources/emitters and evaluation of administrative and engineering controls to assure personnel safety are made by local installation personnel. Remote sites receive consultant support from "attending" personnel from larger installations. Where additional equipment, analytical, or personnel requirements exist that are beyond the capability of local installations, consultant support is provided by designated laboratories or specialized teams. The USAF Occupational and Environmental Health Laboratory provides equipment loan, analytical capability and field consultant and measurement service Air Force-wide on health related problems resulting from both ionizing and non-ionizing radiation. The Air Force Communications Service provides field measurements and consultant service for health hazard evaluation and for electromagnetic interference.

Adequate instrumentation for almost all routine monitoring of ionizing radiation sources has been available and maintained at local installations since well before 1968. As manufacturers have improved their instruments, upgrading of instrumentation has been accomplished. Workload for surveillance of ionizing radiation sources at the local installation level has remained fairly constant. In the case of non-ionizing radiation, lack of simple, rugged hand-held field survey meters severely limited measurements by the local installation. Consequently, monitoring and surveillance of non-ionizing radiation emitters was minimal. The development and introduction of hand-held, broad band survey instruments into the Air Force has significantly improved our capability.

The continued introduction of such instrumentation, as well as the development of new technology, will create an increasing commitment of resources to monitoring non-ionizing radiation.

APPENDIX H

No Comment

APPENDIX I—COLLECTION AND ANALYSIS OF HEALTH DATA

IONIZING AND NON-IONIZING RADIATION

Epidemiologic studies of persons exposed to radiation are not conducted except when an accident or potential overexposure may have occurred and medical data is collected as part of the investigation to determine if any clinical change was incurred as a result of the exposure.

IONIZING RADIATION

The USAF Occupational and Environmental Health Laboratory provides centralized dosimetry and bioassay services for individual occupational exposure to ionizing radiation. These data are reflective of personnel "health" in that they provide a data base for evaluating "population at risk" exposure levels. Resources shown are essentially those involved with the operation of the USAF Personnel Dosimetry Program including film and thermoluminicent dosimeter processing, record keeping, and radiation exposure control.

NON-IONIZING RADIATION

Positive physical examinations are not considered to be required for occupational exposure below the established PEL's and practical personnel dosimetry has not been demonstrated. Hence, there are no data entries for non-ionizing radiation.

APPENDIX J

No Comments

APPENDIX K—OTHER BIOLOGICAL OR PHYSICAL EFFECTS STUDIES

Reports of electromagnetic interference (EMI) of life sustaining cardiac pacemakers prompted the Chief of Staff, USAF, and the Surgeon General, to direct a study to evaluate all USAF radar and RFR systems. Data were acquired on EMI effects on all major US and West European pacemakers and results were made available to the US Food and Drug Administration and appropriate pacemaker manufacturers. This has resulted in major design changes and improvements in pacer manufacture. Wrap up studies and technology watch efforts will continue in 1977, terminating in 1979.

APPENDIX L

NO COMMENTS

DEPARTMENT OF THE ARMY,
OFFICE OF THE SURGEON GENERAL,
Washington, D.C., June 9, 1977.

Hon. WENDELL H. FORD,
Chairman, Consumer Subcommittee,
U.S. Senate,
Washington, D.C.

DEAR SENATOR FORD: General Taylor has asked me to reply to the letter signed by you and Honorable Adlai E. Stevenson on 20 May 1977 concerning federal radiation research and regulatory programs. I am also sending Senator Stevenson an identical letter.

Information in the matrices is the best estimate of funds expended and in-house man year performance for the US Army Medical Research and Development Command (USAMRDC) and the US Army Environmental Hygiene Agency (USAEHA) during the ten year period requested.

The ionizing radiation project to develop a chemical protector against fallout was terminated during fiscal year 1973. The microwave research program was transferred from the Defense Advanced Research Project Agency (DARPA) to USAMRDC during fiscal year 1972. Laser research was formerly conducted as a joint project between the Army Materiel Command (AMC) and The Surgeon General until fiscal year 1975, when this joint effort was terminated. At that time, USAMRDC initiated a separate laser effects project.

The Office of the Director of Defense Research and Engineering (ODDRE) is consolidating the answers to the four questions and submitting a separate reply.

Sincerely,

ROBERT W. GREEN, M.D.,
Major General, MC,
Acting The Surgeon General.

MICROWAVE

1. *Studies to determine human health effects.*—All studies conducted in this program have been designed to ascertain human health effects but have been conducted using laboratory animals, phantom models or animal tissues. No human subjects research has been conducted. The research program supported by funds shown here include:

(*a*) Microwave energy absorption and distribution in experimental animals and manikin models.

(*b*) Microwave effects on nervous and sensory systems.

(*c*) Microwave effects on behavior and performance.

(*d*) Stress reaction resulting from microwave radiation.

(*e*) Dosimetry for recording and evaluating microwave radiants.

2. *Other biological or physical effects.*—These studies support neuropsychiatric research programs in biochemical analysis and enzyme inactivation.

3. *Other studies.*—Funds here have been used to develop and maintain a comprehensive data base of world literature related to biological effects of electromagnetic radiation. This has been a joint effort of several federal agencies and in FY 77 has been assumed by the Office of Telecommunications Policy.

4. All other columns are not applicable to the Army medical department research program.

DOLLARS IN THOUSANDS

NON-IONIZING RADIATION (MICROWAVE) e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)	0 0 132 132	IN-HOUSE MONEY SPENT MAN YEARS EXTRAMURAL MONEY SPENT TOTAL MONEY SPENT										
1969 Extra-Mural (Funds) Total Funds	0 0 131 131	"	"									
1970	0 0 112 112	"	"									
1971	0 0 74 74	"	"									
1972	200 6 20 220	"	"									0 0 86 86
1973	380 8 48 428	"	"									0 0 108 108
1974	470 9 57 527	"	"								0 0 92 92	0 0 153 153
1975	560 8 158 718	"	"								0 0 40 40	0 0 33 33
1976	599 10 192 791	"	"								0 0 15 15	0 0 4 4
1977	694 12 214 908	"	"								20 0 10 30	
Est. 1978	543 13 267 [illegible]	"	"								30 0 10 [illegible]	

applies to all years

LASER

1. *Other biological or physical effects studies.*—All studies have been conducted utilizing laboratory animals, phantom models or animal tissue. Data generated are to be used to extrapolate human health effects of laser radiation. No research has been conducted on human subjects. Laser research is conducted in the following areas:

(a) Ocular effects of laser radiation.

(b) Behavioral effects of laser irradiation.

(c) Laser effects on skin and cutaneous tissue.

Primary research is conducted with three laser frequencies: carbon dioxide, gallium arsenide and neodymium.

2. *Other studies.*—This program was designed to develop specialized instruments for use in the study of biologic effects of laser radiation. The information in this column could have been entered in Column 1, but since research was not conducted on human subjects, it seemed appropriate to consider it as other biological effects. All final data is used to extrapolate effects to the human, however.

3. No other column on the matrix is applicable to the Army medical department laser research program.

NON-IONIZING RADIATION (LASER)

Year	Studies to determine human health effects	Ecological effects Animal, Plant	Agricultural Effects Plant/Animal	Criteria and/or Standards Development	State/Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain) e.g. microwave	Other Studies (Explain)
1968											185 4 237 422	92 1 0 92
1969											318 7 297 646	95 1 0 95
1970											349 8 182 610	60 1 0 60
1971											337 7 274 611	26 2 0 26
1972											428 6 182 610	42 2 0 42
1973											462 3 64 526	27 1 0 27
1974											400 1 265 665	
1975											587 8 433 1070	
1976											588 10 425 1013	
1977											395 10 600 995	
Est.											415 8 700 1115	

In-House (Positions)
Extra-Mural (Funds)
Total Funds
applies to all years

NOTE: DOLLARS IN THOUSANDS

IN-HOUSE MONEY SPENT
MAN YEARS
EXTRAMURAL MONEY SPENT
TOTAL MONEY SPENT

IONIZING RADIATION

1. The Army medical department program in ionizing radiation was designed to develop a chemical means of protection against the effects of ionizing radiation. Primarily, the purpose was directed at protection against Beta and Gama radiation resulting from nuclear weapons employment and fallout resulting from nuclear weapons detonation.

2. *Other biological and physical effects.*—The research conducted was for the synthesis of new chemical structures which might provide protection against radiation. Biological screening of these chemicals as well as other chemical substances was conducted on small animals, primarily rodents, and on primate models to determine efficacy of the chemicals. In addition to these projects, research was conducted, using human subjects, to determine tolerance to the chemicals. No human subjects were exposed to radiation.

3. *Other studies.*—Two studies were conducted. One was a study, using an operational scenario, to determine the usefulness of chemical protection; but it was inconclusive. The second study involved ad hoc committees looking at three aspects of the therapy of radiation injury: immunologic aspects, early indicators and metabolic aspects. The information in this column could have been entered in Column 1, but since research was not conducted on human subjects, it seemed appropriate to consider it as other biological effects. All final data is used to extrapolate effects to the human, however.

4. No other columns on the matrices are applicable to the Army medical department ionizing radiation research program.

IONIZING RADIATION

DOLLARS IN THOUSANDS

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)											375 10 781 1156	0 0 40 40
1969 Extra-Mural (Funds) Total Funds											375 10 1049 1424	0 0 40 40
1970											300 8 994 1294	0 0 49 49
1971						NOTE:	IN-HOUSE MONEY SPENT MAN·YEARS EXTRAMURAL MONEY SPENT TOTAL MONEY SPENT				150 3 511 661	0 0 75 75
1972											150 3 382 532	
1973											150 3 164 314	
1974											138 2 5 143	
1975											0 0 5 5	
1976												
1977												
Est.												

applies to all years

Incl 1 to 3

BRIEF DESCRIPTION OF USAEHA ACTIVITIES IN THE PROJECTS LISTED ON THE MATRIX DATA SHEETS

1. Studies to Determine Human Health Effects: Ocular effects surveillance.

2. Ecological Efforts, Animal/Plant: NA

3. Agricultural Effects, Plant/Animal: NA

4. Criteria and/or Standards Development: Preparation of DA standards documents and participation in national standards committees such as those of the American National Standards Institute.

5. State/Federal Liaison: Liaison and coordination with State and Federal agencies such as the Bureau of Radiological Health, the Department of Labor, the National Institute of Occupational Safety and Health, the US Environmental Protection Agency and the Nuclear Regulatory Commission.

6. Licensing, Certification, Inspection: Review of Nuclear Regulatory Commission license applications, DA authorizations, certification training of DA personnel, and participation in formal general inspections.

7. Monitoring and/or Surveillance: Activity/installation radiation protection surveys, equipment special studies and evaluations, and evaluations of radioactive commodities.

8. Medical Diagnostic, Therapeutic: That portion of the ionizing and nonionizing radiation protection programs applicable to these medical devices.

9. Collection and/or Analysis of Health Data: Analysis of samples collected from personnel occupationally exposed to radioactive material.

10. Collection and/or Analysis of Environmental Data: Analysis of environmental samples for compliance with air and water quality standards.

11. Other Biological or Physical Effects Studies (Explain): NA

12. Other Studies (Explain): Training in all aspects of radiation protection conducted by this Agency.

US ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MD 21010

NONIONIZING RADIATION (ULTRASOUND)

NOTE: Dollars in Thousands

Year	Studies to Determine Human Health Effects	Ecological Efforts Animal/Plant	Agricultural Effects Animal/Plant	Criteria and/or Standards Development	State/Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diag-Therapeutic	Collection and/or Analysis of Health Data	Collection and/or Analysis of Environmental Data	Other Biological or Physical Effects Studies (Explain)	Other Studies (Explain)
1968												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1969												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1970												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1971												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1972												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1973												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1974												
In-House ($)												
Extramural ($)												
Total ($)												
Man-years												
1975												
In-House ($)				5.2	5.2			12.8				
Extramural ($)				0	0			0				
Total ($)				5.2	5.2			12.8				
Man-years				0.2	0.2			0.5				
1976												
In-House ($)				9.2	4.6			22.8				
Extramural ($)				0	0			0				
Total ($)				9.2	4.6			22.8				
Man-years				0.4	0.2			1.0				
1977												
In-House ($)				11.0	5.5			24.8				
Extramural ($)				0	0			0				
Total ($)				11.0	5.5			24.8				
Man-years				0.4	0.2			1.0				
Est. 1978												
In-House ($)				15.0	9.0			30.0				
Extramural ($)				0	0			0				
Total ($)				15.0	9.0			30.0				
Man-years				0.5	0.3			1.0				

US ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MD 21010

NONIONIZING RADIATION (MICROWAVE/RADIOFREQUENCY)

NOTE: Dollars in Thousands

Year	Studies to Determine Human Health Effects	Ecological Efforts Animal/Plant	Agricultural Effects Animal/Plant	Criteria and/or Standards Development	State/Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diag-Therapeutic	Collection and/or Analysis of Health Data	Collection and/or Analysis of Environmental Data	Other Biological or Physical Effects Studies (Explain)	Other Studies (Explain)
1968												
In-House ($)				1.7	2.7		39.4	0.5				3.4
Extramural ($)				0	0		0	0				0
Total ($)				1.7	2.7		39.4	0.5				3.4
Man-years				0.1	0.2		1.5	0.1				0.2
1969												
In-House ($)	12.0			4.0	2.0		30.2	0.5				3.9
Extramural ($)	0			0	0		0	0				0
Total ($)	12.0			4.0	2.0		30.2	0.5				3.9
Man-years	0.2			0.3	0.2		2.2	0.1				0.3
1970												
In-House ($)	40.0			6.1	7.6		67.6	2.3				7.6
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			6.1	7.6		67.6	2.3				7.6
Man-years	0.6			0.3	0.3		2.8	0.1				0.3
1971												
In-House ($)	40.0			6.5	8.1		67.0	4.1				8.1
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			6.5	8.1		67.0	4.1				8.1
Man-years	0.6			0.3	0.3		2.1	0.2				0.2
1972												
In-House ($)	40.0			10.9	5.5		87.8	6.0				8.8
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			10.9	5.5		87.8	6.0				8.8
Man-years	0.6			0.4	0.2		2.9	0.2				0.3
1973												
In-House ($)	40.0			16.0	4.8		148.2	8.0				16.0
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			16.0	4.8		148.2	8.0				16.0
Man-years	0.6			0.8	0.2		5.4	0.4				0.8
1974												
In-House ($)	40.0			23.4	4.7		193.4	18.7				35.1
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			23.4	4.7		193.4	18.7				35.1
Man-years	0.6			1.0	0.2		6.2	0.8				1.4
1975												
In-House ($)	40.0			25.6	5.2		198.4	25.6				25.6
Extramural ($)	0			0	0		0	0				0
Total ($)	40.0			25.6	5.2		198.4	25.6				25.6
Man-years	0.6			0.9	0.2		5.0	0.9				0.9
1976												
In-House ($)	55.0			9.2	4.6		149.7	34.2				11.4
Extramural ($)	0			0	0		0	0				0
Total ($)	55.0			9.2	4.6		149.7	34.2				11.4
Man-years	0.8			0.4	0.2		5.5	1.5				0.5
1977												
In-House ($)	6.0			13.8	13.8		134.8	27.5		5.0		19.3
Extramural ($)	0			0	0		0	0		36.0		0
Total ($)	6.0			13.8	13.8		134.8	27.5		41.0		19.3
Man-years	0.1			0.9	0.5		4.4	1.0		1.1		0.7
[illegible] 1978												
In-House ($)				15.0	15.0		156.0	30.0		5.0		24.0
Extramural ($)				0	0		0	0		72.0		0
Total ($)				15.0	15.0		156.0	30.0		77.0		24.0
Man-years				0.5	0.5		4.0	1.0		2.0		1.0

US ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MD 21010

IONIZING RADIATION

NOTE: Dollars in Thousands

Year	Studies to Determine Human Health Effects	Ecological Efforts Animal/Plant	Agricultural Effects Animal/Plant	Criteria and/or Standards Development	State/Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diag-Therapeutic	Collection and/or Analysis of Health Data	Collection and/or Analysis of Environmental Data	Other Biological or Physical Effects Studies (Explain)	Other Studies (Explain)
1968												
In-House ($)						11.9	55.4	55.0	13.0	31.2		
Extramural ($)						0	0	0	0	0		
Total ($)						11.9	55.4	55.0	13.0	31.2		
Man-years						0.7	4.8	3.5	1.0	1.0		
1969												
In-House ($)						12.1	55.8	60.3	12.6	30.3		
Extramural ($)						0	0	0	0	0		
Total ($)						12.1	55.8	60.3	12.6	30.3		
Man-years						0.7	4.8	3.5	1.0	1.0		
1970												
In-House ($)				7.0		7.0	68.9	70.2	21.1	50.6		
Extramural ($)				0		0	0	0	0	0		
Total ($)				7.0		7.0	68.9	70.2	21.1	50.6		
Man-years				0.5		0.5	3.5	3.5	1.0	1.0		
1971												
In-House ($)				10.3		12.4	61.4	72.4	19.6	47.1		
Extramural ($)				0		0	0	0	0	0		
Total ($)				10.3		12.4	61.4	72.4	19.6	47.1		
Man-years				0.5		0.6	3.9	3.5	2.0	2.5		
1972												
In-House ($)				8.8		8.8	61.8	70.3	15.1	36.3		
Extramural ($)				0		0	0	0	0	0		
Total ($)				8.8		8.8	61.8	70.3	15.1	36.3		
Man-years				0.5		0.5	3.5	4.0	1.5	4.0		
1973												
In-House ($)				17.0		17.0	110.2	101.9	42.2	101.3		
Extramural ($)				0		0	0	0	0	0		
Total ($)				17.0		17.	110.2	101.9	42.2	101.3		
Man-years				1.0		1.0	5.5	6.0	1.5	5.0		
1974												
In-House ($)				64.1		32.0	122.9	137.9	44.6	107.0		22.4
Extramural ($)				0		0	0	0	0	0		0
Total ($)				64.1		32.0	122.9	137.9	44.6	107.0		22.4
Man-years				2.0		1.0	4.0	4.3	2.0	6.0		0.7
1975												
In-House ($)				50.9		35.6	141.5	137.4	57.6	138.3		25.4
Extramural ($)				0		0	0	0	0	0		0
Total ($)				50.9		35.6	141.5	137.4	57.6	138.3		25.4
Man-years				1.0		0.7	2.6	2.7	2.0	6.0		0.5
1976												
In-House ($)				59.2		29.1	84.8	96.1	44.3	106.3		20.4
Extramural ($)				0		0	0	0	0	0		0
Total ($)				58.2		29.1	84.8	96.1	44.3	106.3		20.4
Man-years				2.0		1.0	3.0	3.3	1.0	5.0		0.7
1977												
In-House ($)				26.1		22.6	119.7	97.1	52.5	117.6		15.8
Extramural ($)				0		0	0	0	0	0		0
Total ($)				26.1		22.6	119.7	97.1	52.5	117.6		15.8
Man-years				1.1		1.0	5.0	4.3	2.1	6.0		0.7
Est. 1978												
In-House ($)				27.9		24.4	154.4	129.3	74.1	169.6		17.1
Extramural ($)				0		0	0	0	0	0		0
Total ($)				27.9		24.4	154.4	129.3	74.1	169.6		17.1
Man-years				1.1		1.0	6.0	5.3	2.1	6.0		0.7

US ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MD 21010

NONIONIZING RADIATION (LASER AND HIGH INTENSITY LIGHT SOURCES)

NOTE: Dollars in Thousands

Year	Studies to Determine Human Health Effects	Ecological Efforts Animal/Plant	Agricultural Effects Animal/Plant	Criteria and/or Standards Development	State/Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diag-Therapeutic	Collection and/or Analysis of Health Data	Collection and/or Analysis of Environmental Data	Other Biological or Physical Effects Studies (Explain)	Other Studies (Explain)
1968												
In-House ($)				12.6	6.3		63.2					6.3
Extramural ($)				0	0		0					0
Total ($)				12.6	6.3		63.2					6.3
Man-years				0.6	0.3		1.8					0.3
1969												
In-House ($)	6.0			11.8	3.0		43.0					5.9
Extramural ($)	0			0	0		0					0
Total ($)	6.0			11.8	3.0		43.0					5.9
Man-years	0.1			0.8	0.2		2.6					0.4
1970												
In-House ($)	20.0			18.5	9.3		74.2					9.3
Extramural ($)	0			0	0		0					0
Total ($)	20.0			18.5	9.3		74.2					9.3
Man-years	0.3			0.8	0.4		2.4					0.4
1971												
In-House ($)	20.0			14.8	9.8		75.0					9.9
Extramural ($)	0			0	0		0					0
Total ($)	20.0			14.8	9.8		75.0					9.9
Man-years	0.3			0.5	0.3		2.3					0.4
1972												
In-House ($)	20.0			14.6	7.3		49.0	3.6				3.6
Extramural ($)	0			0	0		0	0				0
Total ($)	20.0			14.6	7.3		49.0	3.6				3.6
Man-years	0.3			0.6	0.3		1.8	0.1				0.2
1973												
In-House ($)	20.0			13.0	6.5		128.0	2.6				6.5
Extramural ($)	0			0	0		0	0				0
Total ($)	20.0			13.0	6.5		128.0	2.6				6.5
Man-years	0.3			0.6	0.3		5.1	0.1				0.4
1974												
In-House ($)	20.0			11.7	4.7		233.0	14.0				11.7
Extramural ($)	0			0	0		0	0				0
Total ($)	20.0			11.7	4.7		233.0	14.0				11.7
Man-years	0.3			0.5	0.2		7.4	0.5				0.5
1975												
In-House ($)	20.0			10.5	4.2		208.0	10.5				10.5
Extramural ($)	0			0	0		0	0				0
Total ($)	20.0			10.5	4.2		208.0	10.5				10.5
Man-years	0.3			0.4	0.2		6.6	0.5				0.5
1976												
In-House ($)	35.0			16.5	18.6		151.0	9.3				7.5
Extramural ($)	0			0	0		0	0				0
Total ($)	35.0			16.5	18.6		151.0	9.3				7.5
Man-years	0.5			0.7	0.9		6.2	0.4				0.4
1977												
In-House ($)	3.5			11.5	4.8		137.0	8.0		2.0		9.6
Extramural ($)	0			0	0		0	0		0		0
Total ($)	3.5			11.5	4.8		137.0	8.0		2.0		9.6
Man-years	0.1			0.5	0.3		6.8	0.4		0.1		0.5
Est. 1978												
In-House ($)				14.7	4.8		150.0	8.0		2.0		9.6
Extramural ($)				0	0		0	0		0		0
Total ($)				14.7	4.8		150.0	8.0		2.0		9.6
Man-years				0.7	0.3		6.6	0.4		0.1		0.5

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY,
Arlington, Va.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology and Space Subcommittee, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR SENATOR STEVENSON: Thank you for your letter of May 20 requesting information relating to radiation health and safety research. During the perod from 1965 to 1971 we supported Project Pandora which was concerned with reviewing the safety levels associated with microwave radiation, and I have enclosed a summary of this project.

Since the programs of our Agency are directed toward advancing technology for future military systems, we do not normally support research associated with radiation health and safety. In the future, we do not plan to undertake programs in the area of radiation health and safety research, and the specific questions you pose are not ones to which we can contribute meaningful information.

I hope this information will be helpful to you and the members of the committee.

Sincerely,

GEORGE H. HEILMEIER,
Director.

NON-IONIZING RADIATION

HUMAN HEALTH EFFECTS

Title: Project Pandora.

During the period 1965–1971 Defense Advanced Research Projects Agency sponsored Project Pandora which was concerned with the biological effects of microwaves and investigated the adequacy of established safety levels for normal working exposure to radio frequency radiation. When it became apparent that established U.S. standards for radiation exposure were adequate and that no new effects could be observed, the project was terminated.

Funding:

Fiscal year 1968	$925,000
Fiscal year 1969	464,000
Fiscal year 1970	367,000
Fiscal year 1971	200,000

DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING,
Washington, D.C.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology and Space Subcommittee,
U.S. Senate, Washington, D.C.

DEAR SENATOR STEVENSON: This is in response to your joint letter with Senator Wendell H. Ford of 20 May 1977 concerning federal radiation research and regulating programs. I understand that the individual Military Surgeons General were also requested to respond on this subject and my staff has coordinated this response at the working level to avoid providing you duplicative information. Specifically, the Services will supply the detailed matrix data requested by your enclosure, since these data represent the total of the DoD effort. Attachment 1 contains my response to the four questions posed. Each Surgeon General may provide supplemental answers in areas of unique Service concern.

Should additional information be required, please contact me. I will be pleased to designate a witness to testify for all DoD at the hearings in June if you so desire.

Sincerely,

WILLIAM J. PERRY.

Attachment.

Responses to questions posed by Committee on Commerce, Science and Transportation, U.S. Senate regarding federal research and regulatory programs.

Question (1) What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Response (1) There have been numerous changes in federal agency jurisdiction on the control of ionizing and non-ionizing radiation health hazards that have impacted DoD programs, and in varying degrees increased our overall efforts. Most notable are: the enactment of PL 90–602 which established electronic product emission standards; the enactment of PL 91–190, the National Environmental Policy Act which requires all federal agencies to assess their proposed or continuous actions for environmental consequences; the President's reorganization Plan #3 establishing the Environmental Protection Agency (EPA) and transference of the Federal Radiation Council functions to the EPA; and the establishment of the Office of Telecommunications Policy (OTP) which formed the Electromagnetic Radiation Management Advisory Council (ERMAC) to advise on possible side effects and the adequacy of control of electromagnetic radiations associated with use of the electromagnetic spectrum. The Defense Department has a high degree of awareness of the potential health hazards associated with the development of weapon systems that emit electromagnetic radiation. Definitive measures have been instituted early in the systems acquisition phase to eliminate emissions that are not necessary for weapon system effectiveness. The most significant action resulting from changes in federal policy has been the ERMAC's initiation of a multi-agency federal government effort to evaluate the effects that electromagnetic radiation has on living organisms under different exposure conditions, determine the clinical significance of these data, assess the hazard associated with any observed effects and establish a rational scientific basis and guidelines for developing appropriate control measures. The DoD has participated in this interagency activity maintaining a full awareness of other federal agency research programs. Through this cognizance, unnecessary duplication is avoided and the data generated is shared by all.

Question (2) Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

Response (2) There is no required formalized contact with the states with regards to occupational radiological health matters since under OSHA, the states have no primacy over federal activities even when the states have an approved program. This is also true with respect to use or radionuclides under an NRC license vis-a-vis agreement states.

In the area of environmental quality, the DoD is bound to comply with federal or state and local requirements, whichever are more stringent. The formal interface with state and local agencies is accomplished by each military installation through the regional office of the EPA. Again, as a matter of professional courtesy, interchange with state offices is encouraged by DoD in areas of mutual interest. Confusion concerning respective responsibility where it has existed has been readily resolved to date.

Question (3) Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Response (3) The existing federal radiation regulatory programs could be significantly improved if the jurisdiction of each federal agency having regulatory authority was more clearly defined. The Department of Labor (OSHA), the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Food and Drug Administration (BHR and BMD) each have legislative authority apparently with some overlapping areas of responsibility. Priority attention to this matter would prevent confusion in the future when new non-ionizing radiation standards are proposed.

Another factor which bears attention is the lack of consistency between standards proposed by the regulatory agencies. Any electromagnetic radiation product emission, occupational or environmental standard, must be consistent with all other standards based on reliable research data and capable of withstanding peer review. There is a growing tendency amongst the federal agencies controlling radiation hazards to propose standards in the absence of reproducible data demonstrating clinically significant effects or reliable epidemiological data that suggests the current standards are not safe.

Regarding funding levels, the increased interest in the effects of exposure to non-ionizing radiation has prompted the DoD to review its bioeffects research program and develop a tri-Service research plan. The plan assures that each

Service's research program complement each other, are responsive to weapon system requirements under development and identify resources needed to accomplish the program objectives. The DoD has initiated a program with congressional approval to increase the technology base funding which should provide the additional resources needed to enhance the bioeffects research program.

Question (4) What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

Response (4) Superficially, it might appear that a consolidated federal radiation agency tasked with all research and regulatory responsibility is the proper solution to the apparent confusion in this area. However, removal of defense systems biomedical research from DoD would be detrimental to the timely development of weapons systems. Also, there is a hazard of conflict of interest in any single agency being responsible for basic research, technology development as well as regulatory activity. Congress recently separated the former Atomic Energy Commission into two separate agencies, apparently for this reason. I believe that explicit delineation of regulation responsibilities by Congress amongst the existing federal agencies would promote harmony in this area, produce scientifically valid regulations, and properly protect the public.

Defense Nuclear Agency,
Washington, D.C., June 3, 1977.

Hon. Wendell H. Ford,
Chairman, Consumer Subcommittee,
U.S. Senate, Washington, D.C.

Hon. Adlai E. Stevenson,
Chairman, Subcommittee on Science, Technology and Space, U.S. Senate, Washington, D.C.

Dear Senators: I am pleased to respond to your letter of inquiry dated 20 May 1977. Enclosed is information furnished by Colonel LaWayne R. Stromberg, Director of Armed Forces Radiobiology Research Institute (a component of the Defense Nuclear Agency), on the Biomedical Research Program in Ionizing and Nonionizing Radiation of the Defense Nuclear Agency.

If you require any further information, please contact me or Colonel Stromberg at any time.

Sincerely,

R. R. Monroe,
Vice Admiral, U.S. Navy.

Defense Nuclear Agency,
Armed Forces Radiobiology Research Institute,
Bethesda, Md., June 2, 1977.

Hon. Wendell H. Ford,
Chairman, Consumer Subcommittee,
U.S. Senate, Washington, D.C.

Hon. Adlai E. Stevenson,
Chairman, Subcommittee on Science, Technology and Space, U.S. Senate, Washington, D.C.

Dear Senators: We are pleased to provide the information you requested concerning our radiation research program and to comment on the questions asked in your letters of 20 May 1977 to this Institute and to VADM R. R. Monroe, Director, Defense Nuclear Agency.

The Armed Forces Radiobiology Research Institute (AFRRI) was chartered in 1962 to study the biomedical effects of ionizing radiation using sources that would simulate in dose and type that released by the detonation of a nuclear weapon. The present charter, dated 11 May 72 (Incl. 1), defines the AFRRI role in the Department of Defense and its relationship to the nonmilitary scientific community.

RDT&E funding is received from the Defense Nuclear Agency (DNA, formerly the Defense Atomic Support Agency). No operation and management funds are utilized in fulfilling the AFRRI mission. The current DNA Program Definition shows the AFRRI budget as funding element 6.27.04H, entitled "Biomedical Effects." Reimbursable authority to accept non-Defense Nuclear Agency funds is currently $800,000 for FY 77. Incl 2 gives a chronological history of funding and man-years spent on research in ionizing radiation effects. Research into nonionizing radiation effects including work to meet DOD requirements not directly related to nuclear weapons effects was instituted in FY 74. The effort in this area is summarized in Incl 3. This work includes research on the biological effects of exposures to extremely low frequency electrical fields and to microwaves to meet requirements of the U.S. Navy.

With regard to specific questions in your letter, the following comments reflecting the opinions of the AFRRI staff are offered:

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Comment. The primary changes have been the establishment of the Environmental Protection Agency, the implementation of the Occupational Safety and Health Act, the separation of the Atomic Energy Commission into the Energy Research and Development Administration and the Nuclear Regulatory Commission and the transfer of the Federal Radiation Council activities to the Environmental Protection Agency. The overall effect has been to increase the complexity and expense of meeting routine as well as special requirements generated by these different agencies due to the promulgation of additional regulations and a substantial increase in required reports. Since a particular program may well require coordination with several agencies, it may be necessary to seek agreement among agencies that have conflicting goals and viewpoints.

Question 2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

Comment. Our contact with state groups is minimal and is concerned primarily with coordinating emergency planning procedures and responses. This is a relatively simple matter and is not a source of significant confusion or difficulty.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Comment. The present regulation of radiation programs tends to emphasize compliance with detailed regulations covering records keeping and maintenance of documents rather than the actual day-to-day operations. The emphasis of investigations and inspections should be less on detail and more on substantive operational issues.

An additional deficiency that we feel is critical does not relate directly to the regulatory process but has resulted from some of the reorganizations and realignments of functions that have occurred. This is the fact that there is now a critical lack of training courses in radiation safety. At one time the Bureau of Radiological Health sponsored a comprehensive and very valuable series of courses that helped materially in maintaining high standards of operating efficiency and safety. With the transfer of this function to the EPA, a severe deficiency has developed which has only been partially filled by the use of academic and commercial resources.

Question 4. What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

Comment. We feel strongly that a single federal radiation agency responsible for all federal radiation activities should not be formed. In the area of occupational health and safety, radiation is only one of many hazards and is frequently the least important. In medicine and in research, radiation is almost invariably one of the tools used to solve problems and not the basic reason for the research. In certain limited areas, radiation by itself is the fundamental factor, and these areas are quite properly the concern of a highly specialized agency such as the Nuclear Regulatory Commission which has a relatively narrow and well-defined charter. The problem with consolidating all federal radiation activities into one agency is that it would have to cut across too many disciplines and activities, and would require extensive duplication of existing expertise within other organizations.

Radiation problems should be maintained in their proper context and relationship to other problems, and dealt with appropriately by agencies with overall responsibilities or occupational health, environmental quality or medical research, such as the Department of Labor, the Environmental Protection Agency, and the National Institutes of Health, etc. In that way, a proper perspective and relative sense of value can be maintained. That areas of overlapping responsibility and controversy exist is true; however, these can be resolved with time if reasonable opportunity for open debate and discussion between agencies is provided.

I hope the above information is helpful. Should additional material be required, please contact us.

Sincerely,

LAWAYNE R. STROMBERG, MD.,
Colonel, U.S. Army,
Director.

Enclosure.

DEPARTMENT OF DEFENSE DIRECTIVE NO. 510S.33 MAY 11, 1972

Subject: Armed Forces Radiobiology Research Institute (AFRRI)
Reference: (a) DoD Directive 5105.31, "Defense Nuclear Agency (DNA)," November 3, 1971
(b) DoD Directive 5105.33, "Armed Forces Radiobiology Research Institute (AFRRI)," November 20, 1964, (hereby cancelled)

I. GENERAL

A. Established pursuant to the authority vested in the Secretary of Defense the Armed Forces Radiobiology Research Institute (AFRRI) is designated a subordinate unit of the Defense Nuclear Agency (DNA).

B. AFRRI shall serve as a radiobiology research laboratory for the Department of Defense. Other federal and civilian agencies and institutions may utilize AFRRI services as agreed upon by the Secretary of Defense or his designee.

II. MISSION

The mission of AFRRI shall be to conduct scientific research in the field of radiobiology and related matters that are essential to the medical support of the Department of Defense.

III. ORGANIZATION

A. AFRRI shall consist of a Director, a Deputy Director, and a supporting staff.

1. The Director, AFRRI will be a medical department officer in Grade 0–6 nominated by the appropriate Service and appointed by the Director, DNA after consultation with the Board of Governors. Normally, the position of Director will rotate among the Services. His tour of duty shall be consistent with professional and military requirements and applicable DoD Directives and Instructions.

2. The Deputy Director will be an officer in Grade 0–6 or 0–5 from one of the Military Services not represented by the Director.

3. The staff shall be constituted of military and civilian personnel authorized by a Joint Table of Distribution (JTD), developed by the Director, DNA, and approved by the Joint Chiefs of Staff. Insofar as possible, the military members of the supporting staff shall be provided on an equal basis by the Military Departments.

B. In exercising command of AFRRI, the Director, DNA, will be advised in matters of professional policy direction and related matters by a Board of Governors.

1. The AFRRI Board of Governors shall consist of the Director, DNA, as Chairman, and the Chief Surgeons General of the Army, Navy, and Air Force.

2. The Director, National Institutes of Health, and the Director, Division of Biology and Medicine, Atomic Energy Commission, or their designees, may be invited to participate in meetings of the Board of Governors when matters of mutual interest are being considered.

IV. FUNCTIONS

Under the direction, control and authority of the Director, DNA, and in accordance with appropriate DOD Directives and Instructions, AFRRI shall:

A. Operate facilities for conducting research on the biological effects of ionizing and disseminate the results.

B. Conduct advanced training in the field of biological effects of ionizing radiation to meet the internal requirement of the Institute, and those which may be developed and requested by other DOD Components.

C. Operate facilities for the production of short-lived radioisotopes for use in direct or collaborative research performed by the Institute.

D. Perform such other functions as may be assigned.

V. AUTHORITY

The appropriate provisions of reference (a) apply to the Director, DNA, in exercising command of AFRRI and fulfilling the functional responsibilities implicit in this Directve.

VI. ADMINISTRATION

A. The Military Departments will assign military personnel to AFRRI in accordance with approved authorizations. Procedures for such assignments will be as agreed upon between the Director, DNA, and the individual Military Departments.

B. Maintenance and operation of AFRRI normally will be programmed, budgeted and financed by DNA. This provision does not preclude AFRRI from participating in reimbursable activities subject to concurrence by Director, DNA.

C. The pay, allowances (including subsistence) and permanent change of station travel costs of military personnel assigned to AFRRI will be borne by the Military Department from which assigned.

VII. EFFECTIVE DATE AND CANCELLATION

This Directive is effective immediately. Reference (b) is hereby superseded and cancelled.

KENNETH RUSH,
Deputy Secretary of Defense.

IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 In-House (Positions)											236 MY * $4.6 MIL **	
1969 Extra-Mural (Funds) Total Funds											223 MY * $4.2 MIL **	
1970											221 MY * $4.1 MIL **	
1971											216 MY * $4.1 MIL **	
1972											215 MY * $3.7 MIL **	
1973											229 MY * $3.8 MIL **	
1974											237 MY * $3.7 MIL **	
1975											214 MY * $3.7 MIL **	
1976											233 MY * $3.9 MIL **	
1977											229 MY * $5.4 MIL **	
Est. 1978											243 MY * $5.5 MIL **	

applies to all years

These projects support the following goals:

1. Define and evaluate human response to nuclear weapon environments,
2. Define mechanisms of radiation injury,
3. Minimize or alleviate the deleterious effects of radiation by development of preventive or therapeutic measures, and
4. Correlate and apply biomedical research data to operational problems.

* MY includes Military Personnel

** Dollars doesn't include Military Pay

INCL #2

NON-IONIZING RADIATION*

*(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing; Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 In-House (Positions)												
1969 Extra-Mural (Funds) Total Funds												
1970												
1971												
1972												
1973												
1974						These projects were done for other governmental agencies on a reimbursable basis. A copy of the DD 1498 (Research and Technology Work Unit Summary) is attached.					6.1 MY* $198,000**	
1975											9.6 MY* $480,000**	
1976											7.8 MY* $ 80,000**	
1977											2.3 MY* $105,000**	
Est. 1978												

applies to all years

* MY includes Military Personnel
** Dollars doesn't include Military Pay

INCL #3

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY

1. AGENCY ACCESSION	DH090032	2. DATE OF SUMMARY	21 Aug 75	REPORT CONTROL SYMBOL	T26262		
3. DATE PREV SUMMARY	4. KIND OF SUMMARY	5. SUMMARY SCTY	6. WORK SECURITY	7. REGRADING	8. DISB'N INSTR'N	9. DATA - CONTRACTOR ACCESS	10. LEVEL OF SUM
01 Sep 74	K. Completion	U	U		NL	☒ YES ☐ NO	A. WORK UNIT

10. NO./CODES	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C903	09
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)*

(U) BIOLOGICAL EFFECTS OF PULSED ELECTROMAGNETIC FIELDS

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*

005900 ENVIR BIOLOGY 012900 PHYSIOLOGY 017100 WPNS EFF

13. START DATE	14. ESTIMATED COMPLETION DATE	15. FUNDING AGENCY	16. PERFORMANCE METHOD
JUL 72	JUL 76	DH	C. IN-HOUSE

17. CONTRACT/GRANT

a. DATES/EFFECTIVE: EXPIRATION:

b. NUMBER:*

c. TYPE: d. AMOUNT:

e. KIND OF AWARD: f. CUM. AMT. $0

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING 1974	3.4	$ 141
	CURRENT 1975	1.7	$ 77

19. RESPONSIBLE DOD ORGANIZATION 034700 2406

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

RESPONSIBLE INDIVIDUAL

NAME: BAUM, S.J.

TELEPHONE: 202-295-1352

21. GENERAL USE

21A. 8 D. E.

20. PERFORMING ORGANIZATION 034700 2406

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)

NAME:* BAUM, S.J.

TELEPHONE: 202-294-1352

SOCIAL SECURITY ACCOUNT NUMBER:

ASSOCIATE INVESTIGATORS

NAME:

NAME: WYANT, D.E.

22. KEYWORDS (Precede EACH with Security Classification Code) (U) PULSED ELECTROMAGNETIC RADIATION (U) HEMATOLOGY: (U) MALIGNANCY: (U) CHROMOSOMES:

23. TECHNICAL OBJECTIVE.* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

OBJECTIVE: (U) To determine biological hazards associated with a long term exposure in an electromagnetic pulsed field. Data is required for evaluating potential occupational hazards associated with long term exposures to electromagnetic pulsed fields.

APPROACH: (U) Sixty male leukemia prone mice (AKA-J), 20 Mammary tumor prone female sprague-dawley rats and 150 male rats to be serially sacrificed for bioassay data will be exposed continuously (23 hr/day) in an EMP field for about a year. An equal number of animals will serve as controls. The exposure will consist of one pulse/second with a peake field intensity up to 500 KV/M with a mixed frequency component up to 100 MHZ. Data will be evaluated to determine if any abnormal biological effects such as an increased incidence and rate of neoplasms, changes in hamatological parameters, increased chromosomal aberrations, etc., occured during the exposure period.

PROGRESS: (U) JUL 73-JUN 75: Publications: Continuous exposure to rodents to 100 million pulses of electromagnetic radiation. AFRRI SR73-23, Health Physics 26:391-398, 1974: Biological effects on rodents exposed to pulsed electromagnetic radiation, AFRRI SR-73-10; Biological measurements in rodents exposed continuously throughout their adult life to pulsed electromagnetic radiation.' AFRRI SR75-11; Health Physics (1975) (in press).

*Available to contractors upon originator's approval

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY

1. AGENCY ACCESSION*: DH 090224

2. DATE OF SUMMARY*: 76 10 01

EXPORT CONTROL SYMBOL: DD-DR&E(AR)636

3. DATE PREV SUM'RY:

4. KIND OF SUMMARY: A. NEW

5. SUMMARY SCTY*: U

6. WORK SECURITY*: U

7. REGRADING*:

8. DISB'N INSTR'N: NL

8b. SPECIFIC DATA-CONTRACTOR ACCESS: ☑ YES ☐ NO

9. LEVEL OF SUM: A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C 303	09
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)*: (U) MICROWAVE CATARACTOGENESIS

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*: 002300 Biochemistry 014100 Radiobiology 007900 Indust.(occup.) Medicine

13. START DATE: 76 10

14. ESTIMATED COMPLETION DATE: 78 09

15. FUNDING AGENCY: DH | DN

16. PERFORMANCE METHOD: C. IN-HOUSE

17. CONTRACT/GRANT

a. DATES/EFFECTIVE:

EXPIRATION:

b. NUMBER:*

c. TYPE:

d. AMOUNT:

e. KIND OF AWARD:

f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING		
	CURRENT 77	3.9	30

19. RESPONSIBLE DOD ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

RESPONSIBLE INDIVIDUAL

NAME: Blasco, A. P. LTC

TELEPHONE: 202-295-1337

21. GENERAL USE

20. PERFORMING ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)

NAME:* Oosta, G. M.

TELEPHONE: 202-295-1335

SOCIAL SECURITY ACCOUNT NUMBER:

ASSOCIATE INVESTIGATORS

NAME: Mathewson, N.S.

NAME: Henry, F. H.

22. KEYWORDS (Precede EACH with Security Classification Code) (U)Microwave; (U)Cataractogenesis; (U)Lens; (U)Proteins; (U)Albuminoid; (U)Crystallins; (U)Rabbit;

23. TECHNICAL OBJECTIVE,* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives:To determine (1)effect of microwave radiation on proteins in rabbit lens; (2)relationship between expected microwave-induced alterations of lenticular proteins and duration of exposure at constant power density.

24.(U)Approach:Test animals will be exposed to subcataractogenic and cataractogenic levels of 2.45 GHz radiation. Possible conversion of soluble lens proteins to an insoluble form during microwave-induced cataractogenesis will be investigated. Quantity of soluble protein will be determined after extraction of all soluble lens proteins in a suitable solvent. Variables in extraction procedure will be studied to determine if soluble protein is converted to insoluble protein by extraction procedure itself. After suitable extraction of lens proteins, quantity of alpha, beta, and gamma crystallins will be measured to determine possible alterations in protein concentration in rabbit lens as result of microwave insult. Each crystallin will be further analyzed to determine shifts in subunit composition and changes in chemical/physical properties attributable to microwave damage.

25.(U)Progress: None. (Ref. FY76 DH090106 MC90109).

*Available to contractors upon originator's approval

DD FORM 1498, 1 MAR 68 PREVIOUS EDITIONS OF THIS FORM ARE OBSOLETE. DD FORMS 1498A, 1 NOV 65 AND 1498-1, 1 MAR 68 (FOR ARMY USE) ARE OBSOLETE. ☆ U.S. GPO: 1974-540-843/8681

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY	1. AGENCY ACCESSION*	2. DATE OF SUMMARY*	REPORT CONTROL SYMBOL
	DH 090225	76 10 01	DD-DR&E(AR)636

3. DATE PREV SUM'RY	4. KIND OF SUMMARY	5. SUMMARY SCTY*	6. WORK SECURITY*	7. REGRADING*	8. DISB'N INSTR'N	8b. SPECIFIC DATA-CONTRACTOR ACCESS	9. LEVEL OF SUM
	A. NEW	U	U		NL	☒ YES ☐ NO	A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C 303	10
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)*

(U) Extremely Low Frequency Studies in Rats

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*

002300 Biochemistry 005900 Environmental Biology 005500 Electricity and Magnetism

13. START DATE	14. ESTIMATED COMPLETION DATE	15. FUNDING AGENCY			16. PERFORMANCE METHOD
76 10	7809	DH	DN		C. IN-HOUSE

17. CONTRACT/GRANT

a. DATES/EFFECTIVE: EXPIRATION:

b. NUMBER:*

c. TYPE: d. AMOUNT:

e. KIND OF AWARD: f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING		
	CURRENT 77	3.9	50

19. RESPONSIBLE DOD ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

RESPONSIBLE INDIVIDUAL

NAME: Blasco, A. P.

TELEPHONE: 202-295-1337

21. GENERAL USE

20. PERFORMING ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)

NAME:* Mathewson, N. S.

TELEPHONE: 202-295-1335

SOCIAL SECURITY ACCOUNT NUMBER:

ASSOCIATE INVESTIGATORS

NAME: Oosta, G. M.

NAME: Henry, F. H.

22. KEYWORDS (Precede EACH with Security Classification Code)

(U)Extremely Low Frequency Radiation; (U)Rats; (U)Weight Gain Effects; (U)Serum Biochemistry

23. TECHNICAL OBJECTIVE,* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives:(1)To determine the effect of extremely low frequency (ELF) electric field exposure on rats and study biological effects with emphasis on the mechanism of action. (2)To determine whether a relationship exists between ELF electric field-induced biological effects and the ELF electric field intensity.

24.(U)Approach:Rats will be exposed to a sinusoidal vertical electric field at 45 Hz initially, at 20 V/m (RMS). The environment, growth and health of the rats, and their food and water consumption will be monitored. At the termination of an irradiation period, serum samples will be taken. Serum analyses including total protein, globulin hematocrit, triglycerides, total free fatty acids, and cholesterol will be determined for each animal.

25.(U)Progress:None. (Ref. FY76 DH090122 MC90110).

*Available to contractors upon originator's approval

DD FORM 1 MAR 68 1498 PREVIOUS EDITIONS OF THIS FORM ARE OBSOLETE. DD FORMS 1498A, 1 NOV 65 AND 1498-1, 1 MAR 68 (FOR ARMY USE) ARE OBSOLETE.

U.S. GPO: 1974-540-843/8691

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY	1. AGENCY ACCESSION* DH 090227	2. DATE OF SUMMARY* 76 10 01	REPORT CONTROL SYMBOL DD-DR&E(AR)636

3. DATE PREV SUM'RY	4. KIND OF SUMMARY A. NEW	5. SUMMARY SCTY* U	6. WORK SECURITY* U	7. REGRADING*	8a. DISB'N INSTR'N NL	8b. SPECIFIC DATA-CONTRACTOR ACCESS ☒ YES ☐ NO	9. LEVEL OF SUM A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C 303	12
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)*

(U) MICROWAVE-INDUCED DAMAGE IN THE MAMMALIAN BRAIN

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*

002300 Biochemistry 014100 Radiobiology 002600 Biology

13. START DATE 76 10	14. ESTIMATED COMPLETION DATE 78 09	15. FUNDING AGENCY DH | DN	16. PERFORMANCE METHOD C. IN-HOUSE

17. CONTRACT/GRANT

a. DATES/EFFECTIVE: EXPIRATION:

b. NUMBER:*

c. TYPE: d. AMOUNT:

e. KIND OF AWARD: f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING		
	CURRENT 77	2.3	105

19. RESPONSIBLE DOD ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

RESPONSIBLE INDIVIDUAL

NAME: Blasco, A. P.

TELEPHONE: 202-295-1337

20. PERFORMING ORGANIZATION

NAME:* ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE

ADDRESS:* BETHESDA, MD. 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)

NAME:* Catravas, G. N.

TELEPHONE: 202-295-1350

SOCIAL SECURITY ACCOUNT NUMBER:

ASSOCIATE INVESTIGATORS

NAME:

NAME:

21. GENERAL USE

22. KEYWORDS (Precede EACH with Security Classification Code)

(U) Microwave (U) Neurochemical Alterations (U). Neurotransmitters (U) Enzymes

23. TECHNICAL OBJECTIVE.* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives: To determine the changes in levels of neurotransmitters and activities of enzymes involved in neurotransmitter metabolism in the central nervous system of microwave-irradiated animals.

24.(U)Approach: Studies performed mainly behind the Iron Curtain have indicated that microwave irradiation at low, non-thermal levels result in a number of neurological and behavioral effects in animals and humans. To substantiate Russian data, a systematic study will be conducted to determine if and to what extent neurochemical mechanisms in mammalian brain are affected by exposure of animals to low level microwave radiation. Groups of rats will be exposed to continuous low-level microwave radiation of 2450 MHz and approximately 10 mW/sq.cm. At various postirradiation time intervals levels of acetylcholine, norepinephrine, dopamine, and serotonin will be determined in discrete brain areas of experimental animals and sham-irradiated controls. Radiation-induced changes in activity of brain enzymes, choline acetyltransferase, acetylcholinesterase, tyrosine hydroxylase, cryptophan hydroxylase and monoamine oxidase which are involved in neurotransmitter metabolism, will also be determined. In a new series of experiments effect of microwave radiation on adenylcyclase-cyclic AMP and prostaglandin system will be determined. Micromethodologies currently in our laboratory will be used.

25.(U)Progress: None. (Ref. FY76 DH090142 MC91228).

*Available to contractors upon originator's approval

PREVIOUS EDITIONS OF THIS FORM ARE OBSOLETE. DD FORMS 1498A, 1 NOV 65 AND 1498-1, 1 MAR 68 (FOR ARMY USE) ARE OBSOLETE.

☆ U.S. GPO: 1974-540-343/CG91

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY				1. AGENCY ACCESSION* DH090106	2. DATE OF SUMMARY* 76 10 01		REPORT CONTROL SYMBOL
3. DATE PREV SUM'RY 75 07 01	4. KIND OF SUMMARY K.COMPLETION	5. SUMMARY SCTY* U	6. WORK SECURITY* U	7. REGRADING*	8a. DISB'N INSTR'N	8b. SPECIFIC DATA-CONTRACTOR ACCESS ☐ YES ☐ NO	9. LEVEL OF SUM A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U990AXM	C901	09
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)* (U) Alterations in Lenticular Proteins as Protein Biochemical Indicators of Microwave Induced Cataractogenesis

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*
002300 Biochemistry 014100 Radiobiology 007900 Indust.(occup.) Medicine

13. START DATE	14. ESTIMATED COMPLETION DATE	15. FUNDING AGENCY			16. PERFORMANCE METHOD
74 06	76 09 [illegible]	DH	DN		C. IN-HOUSE

17. CONTRACT/GRANT
a. DATES/EFFECTIVE: EXPIRATION:
b. NUMBER:*
c. TYPE: d. AMOUNT:
e. KIND OF AWARD: f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING 76	2.7	57
	CURRENT		

19. RESPONSIBLE DOD ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst
ADDRESS:* Bethesda, Maryland 20014

RESPONSIBLE INDIVIDUAL
NAME: Blasco, A. P.
TELEPHONE: 202-295-1337

20. PERFORMING ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst.
ADDRESS:* Bethesda, Maryland 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)
NAME:* Oosta, G. M.
TELEPHONE: 202-295-1335
SOCIAL SECURITY ACCOUNT NUMBER:

21. GENERAL USE

ASSOCIATE INVESTIGATORS
NAME: Mathewson, N. S.
NAME: Henry, F. H.

22. KEYWORDS (Precede EACH with Security Classification Code) (U)Microwave; (U)Cataractogenesis; (U)Lens; (U)Proteins; (U)Albuminoid; (U)Crystallins; (U)Rabbit; (U)S-35-Methionine

23. TECHNICAL OBJECTIVE.* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives:To determine (1)effect of microwave radiation on proteins in rabbit lens; (2)relationship between expected microwave-induced alterations of lenticular proteins and duration of exposure at constant power density.

24.(U)Approach:Test animals will be exposed to subcataractogenic and cataractogenic levels of 2.45 GHz radiation. Possible conversion of soluble lens proteins to an insoluble form during microwave-induced cataractogenesis will be investigated. Quantity of soluble protein will be determined after extraction of all soluble lens proteins in a suitable solvent. Variables in extraction procedure will be studied to determine if soluble protein is converted to insoluble protein by extraction procedure itself. After suitable extraction of lens proteins, quantity of alpha, beta, and gamma crystallins will be measured to determine possible alterations in protein concentration in rabbit lens as result of microwave insult. Each crystallin will be further analyzed to determine shifts in subunit composition and changes in chemical/physical properties attributable to microwave damage.

25.(U)Progress:1 Jul 75-1 Oct 76. Research to date has determined an appropriate microwave exposure regimen including exposure time and drug use. Evaluation of protein assay techniques such as pore-limit electrophoresis and SDS-electrophoresis are continuing. Experiments designed to determine appropriate pH, ionic strength and buffer composition are in progress. Experiments designed to evaluate effect of oxygen environment on lens proteins are on going. Equipment and techniques such as adsorption-elution from columns of DEAE cellulose and gel filtration, designed to fractionate lenses into classical components (alpha, beta, and gamma crystallins) are being readied for use in calibrating more sensitive electrophoretic assay systems. Animal irradiations are continuing. (Ref. FY77 DH 090224, MC 30309)

*Available to contractors upon originator's approval

DD FORM 1 MAR 68 1498

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY	1. AGENCY ACCESSION*	2. DATE OF SUMMARY*	REPORT CONTROL SYMBOL
	DH090122	76 10 01	

3. DATE PREV SUM'RY	4. KIND OF SUMMARY	5. SUMMARY SCTY*	6. WORK SECURITY*	7. REGRADING*	8a. DISB'N INSTR'N	8b. SPECIFIC DATA-CONTRACTOR ACCESS	9. LEVEL OF SUM
75 07 01	K. COMPLETION	U	U		N/L	☒ YES ☐ NO	A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C901	10
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)* (U) Studies on Biological Effects of Extremely Low Frequency Electromagnetic Radiation in Rats

12. SCIENTIFIC AND TECHNOLOGICAL AREAS*
002300 Biochemistry 005900 Environmental Biology 005500 Electricity and Magnetism

13. START DATE	14. ESTIMATED COMPLETION DATE	15. FUNDING AGENCY		16. PERFORMANCE METHOD
75 10	76 09	DH	HN	C. IN-HOUSE

17. CONTRACT/GRANT
a. DATES/EFFECTIVE: EXPIRATION:
b. NUMBER:*
c. TYPE: d. AMOUNT:
e. KIND OF AWARD: f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING 76	5.0	237
	CURRENT		

19. RESPONSIBLE DOD ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst.
ADDRESS:* Bethesda, Maryland 20014

RESPONSIBLE INDIVIDUAL
NAME: Blasco, A. P.
TELEPHONE: 202-295-1337

20. PERFORMING ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst.
ADDRESS:* Bethesda, Maryland 20014

PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)
NAME:* Mathewson, N. S.
TELEPHONE: 202-295-1335
SOCIAL SECURITY ACCOUNT NUMBER:

ASSOCIATE INVESTIGATORS
NAME: Oosta, G. M.
NAME: Henry, F. H.

21. GENERAL USE

22. KEYWORDS (Precede EACH with Security Classification Code) (U)Serum Biochemistry; (U)Extremely Low Frequency Radiation; (U)Rats; (U)Weight Gain Effects

23. TECHNICAL OBJECTIVE,* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives:(1)To determine the effect of extremely low frequency (ELF) electric field exposure on rats and study biological effects with emphasis on the mechanism of action. (2)To determine whether a relationship exists between ELF electric field-induced biological effects and the ELF electric field intensity.

24.(U)Approach:Rats will be exposed to a sinusoidal vertical electric field at 45 Hz initially, at 20 V/m (RMS). The environment, growth and health of the rats, and their food and water consumption will be monitored. At the termination of an irradiation period, serum samples will be taken. Serum analyses including total protein, globulin hematocrit, triglycerides, total free fatty acids, and cholesterol will be determined for each animal.

25.(U)Progress:1 Jul 75-1 Oct 76.An irradiator with six identical chambers to expose rats to vertical electric fields at ELF frequencies was constructed. Electric and magnetic fields associated with this irradiator have been characterized. A series of experiments at 45 Hz was completed. Analyses of rat growth rates, food and water consumption and key serum metabolite concentrations and hematology are nearing completion. Experiments to date using 48 control and 48 irradiated animals, suggest that exposure of rats to a vertical sinusoidal electric field strength of 20 V/m (RMS) produces no alteration in any growth, feeding, biochemical, hematological and pathological parameters measured. Fabrication of combined magnetic field, electric field, and ground return current simulation systems with MKS modulator at ELF frequencies is in progress. Report presented at USSI meeting, Boulder, Colorado, October 1975. Paper accepted for publication, Radio Science, 1976. (Ref FY77, DH 090225, MC 30310)

*Available to contractors upon originator's approval

DD FORM 1 MAR 68 1498

RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY	1. AGENCY ACCESSION*	2. DATE OF SUMMARY*	REPORT CONTROL SYMBOL
	DH090142	76 10 01	

3. DATE PREV SUM'RY	4. KIND OF SUMMARY	5. SUMMARY SCTY*	6. WORK SECURITY*	7. REGRADING*	8a. DISB'N INSTR'N	8b. SPECIFIC DATA-CONTRACTOR ACCESS	9. LEVEL OF SUM
75 08 01	K.COMPLETION	U	U		NL	☒ YES ☐ NO	A. WORK UNIT

10. NO./CODES:*	PROGRAM ELEMENT	PROJECT NUMBER	TASK AREA NUMBER	WORK UNIT NUMBER
a. PRIMARY	62704H	U99QAXM	C912	28
b. CONTRIBUTING				
c. CONTRIBUTING				

11. TITLE (Precede with Security Classification Code)* (U)NEUROCHEMICAL ALTERATIONS IN THE CENTRAL NERVOUS SYSTEM OF MAMMALS EXPOSED TO MICROWAVE RADIATION

12. SCIENTIFIC AND TECHNOLOGICAL AREAS* 002300 Biochemistry 014100 Radiobiology 002600 Biology

13. START DATE	14. ESTIMATED COMPLETION DATE	15. FUNDING AGENCY	16. PERFORMANCE METHOD
75 08	76 09	DH | HN	C. IN-HOUSE

17. CONTRACT/GRANT
a. DATES/EFFECTIVE: EXPIRATION:
b. NUMBER:*
c. TYPE: d. AMOUNT:
e. KIND OF AWARD: f. CUM. AMT.

18. RESOURCES ESTIMATE		a. PROFESSIONAL MAN YRS	b. FUNDS (In thousands)
FISCAL YEAR	PRECEDING 76	2.9	166
	CURRENT		

19. RESPONSIBLE DOD ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst.
ADDRESS:* Bethesda, Maryland 20014
RESPONSIBLE INDIVIDUAL
NAME: Blasco, A. P.
TELEPHONE: 202-295-1337

20. PERFORMING ORGANIZATION
NAME:* Armed Forces Radiobiology Research Inst.
ADDRESS:* Bethesda, Maryland 20014
PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution)
NAME:* Catravas, G. N.
TELEPHONE: 202-295-1350
SOCIAL SECURITY ACCOUNT NUMBER:
ASSOCIATE INVESTIGATORS
NAME:
NAME:

21. GENERAL USE

22. KEYWORDS (Precede EACH with Security Classification Code)
(U) Microwave (U) Neurochemical Alterations (U) Neurotransmitters (U) Enzymes

23. TECHNICAL OBJECTIVE,* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.)

23.(U)Objectives:To determine the changes in levels of neurotransmitters and activities of enzymes involved in neurotransmitter metabolism in the central nervous system of microwave-irradiated animals.

24.(U)Approach:Studies performed mainly behind the Iron Curtain have indicated that microwave irradiation at low, non-thermal levels result in a number of neurological and behavioral effects in animals and humans. To substantiate Russian data, a systematic study will be conducted to determine if and to what extent neurochemical mechanisms in mammalian brain are affected by exposure of animals to low-level microwave radiation. Groups of rats will be exposed to continuous low-level microwave radiation of 2450 MHz and approximately 10 mW/sq.cm. At various postirradiation time intervals levels of acetylcholine, norepinephrine, dopamine, and serotonin will be determined in discrete brain areas of experimental animals and sham-irradiated controls. Radiation-induced changes in activity of brain enzymes, choline acetyltransferase, acetylcholinesterase, tyrosine hydroxylase, cryptophan hydroxylase and monoamine oxidase which are involved in neurotransmitter metabolism, will also be determined. In a new series of experiments effect of microwave radiation on adenylcyclase-cyclic AMP and prostaglandin system will be determined. Micromethodologies currently in our laboratory will be used.

25.(U)Progress:Aug 75-Oct 76: An increased sensitivity to brain adenyl cyclase stimulation by PGE was observed. Preliminary measurements of thalamic-hypothalamic tryptophan hydroxylase activity and serotonin levels indicated marginal increases. One technical report has been published. (Ref. FY77 DH 090227, MC 30312)

*Available to contractors upon originator's approval

DD FORM 1 MAR 68 1498

U.S. NUCLEAR REGULATORY COMMISSION,
Washington, D.C., June 24, 1977.

Hon. WARREN MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The NRC staff has prepared the attached response to your letter of May 26, 1977, requesting information on activities of the Nuclear Regulatory Commission in radiation research and regulation. The staff response describes the radiation-related research and regulatory programs conducted by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. We trust that this information will be fully responsive to the questions which you posed. If we can be of further assistance, please do not hesitate to inform us of this.

Sincerely,

MARCUS A. ROWDEN,
Chairman.

NRC STAFF RESPONSE TO QUESTIONS BY SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION, JUNE 1977

BACKGROUND

This paper was prepared by the staff of the Nuclear Regulatory Commission. It responds to an inquiry of May 26, 1977, by Senator Warren Magnuson, Chairman of the Senate Committee on Commerce, Science, and Transportation. The inquiry was in connection with hearings planned by the Committee to review and evaluate Federal radiation research and regulatory programs. The Committee keyed its questions to the period from 1968 to 1977, the years since the enactment of the Radiation Control for Health and Safety Act of 1968 (PL 90-602).

Senator Magnuson's letter requested a tabular matrix of resources to show agency expenditures over the period of interest, and also posed four specific questions concerning NRC jurisdiction, Federal/State coordination, and proposals for improvement of radiation protection programs. Responses to these questions appear in subsequent sections of this staff paper, following a summary of the role of the Nuclear Regulatory Commission in relationship to other Federal and State agencies having radiation protection and public health responsibilities.

ROLE OF NRC

The statutory authorities of the NRC derive from the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and the National Environmental Policy Act of 1969. The basic authorities from the Atomic Energy Act include licensing and regulation of production, use, possession, ownership of special nuclear materials, source material, and byproduct materials, and licensing and control over the manufacture, production, possession, use, importation or exportation of production and utilization facilities.

The term "special nuclear material", as used in the Act and in NRC regulations, covers plutonium, uranium enriched in the isotopes U-233 or U-235, any material artificially enriched in these materials, and other materials as specified by the NRC. The term "source material" generally means uranium (not enriched) or thorium and may apply to other materials as specified by the NRC. The term "byproduct materials" includes any radioactive material (except special nuclear material) produced in or made radioactive by exposure to the radiation incident to the process of producing or utilizing a special nuclear material. For practical purposes, this means any radionuclide produced in a nuclear reactor or by irradiation by special nuclear material. The definition generally excludes certain naturally occurring radioactive materials (except those otherwise defined as source materials) and accelerator produced radioisotopes.

A production facility is any equipment or device or part thereof (as determined by the Commission) capable of producing special nuclear material in such quantity as to be significant to the common defense and security. A utilization facility is a device or part thereof (except an atomic weapon) which employs special nuclear materials in such quantities or in a manner to affect the health and safety of the public or be of significance to common defense or security. As examples of these terms, a nuclear power reactor is classified as a utilization facility and a spent fuel processing plant is considered a production facility.

The regulation of these activities in order to protect public health and safety is achieved through: (1) the formulation of rules and regulations; (2) the implementation of these rules and regulations in individual licensing actions which set forth specific requirements for each licensee; (3) a hearing process for permitting public participation in case-by-case licensing actions; (4) an inspection and enforcement program to insure compliance with the regulations and license conditions, and (5) a confirmatory research program to develop the information required to support the licensing and other regulatory functions.

These activities are coordinated with other Federal and State agencies as explained in detail below. For example, the Environmental Protection Agency (EPA) has a lead role in establishing generally applicable standards for radioactivity in the environment and Federal guidance on radiation protection. The NRC implements standards and guidance of these types developed by EPA. The Commission places particular emphasis on coordinating development of environmental radiation standards with EPA. The Commission also coordinates very closely with ERDA on research activities involving radiation protection and the engineering sciences which are important to the safety of activities regulated by NRC.

The NRC regulatory program for protecting public health and safety from exposures to radiation resulting from routine operations and from releases of radioactive materials to the environment is based on consideration of the need to assure adequate protection to the public health and safety and upon a weighing of societal costs and benefits. The basic objectives of the NRC program for protection against radiation can be summarized as follows:

(*a*) To keep radiation doses from all sources of exposure, other than natural background and medical procedures, below the numerical limits of the radiation protection guides.

(*b*) To avoid unnecessary sources of exposure and to ensure that doses received are justifiable in terms of benefits that would not otherwise have been received.

(*c*) To provide for design and operational control of specific facilities and uses of materials, both individually and in combination, so that the resulting doses are sufficiently low that any further reduction in risk would not be considered to justify the effort required to accomplish it; that is, the doses are "as low as reasonably achievable."

In addition, there is a recent trend to include another basic consideration in the regulatory decision process for radiation protection. That is, the trend to make comparisons of radiation criteria and risks with the criteria and risks associated with non-nuclear environmental pollutants or occupational hazards. This has led to the utilization of new and evolving methods for risk and cost-benefit analysis so that public health and worker protection decisions for a myriad of activities can eventually begin to be made after considering comparability of societal risk and allocation of national resources, in addition to the best available scientific information on health and safety effects.

As a result, the NRC program for regulation of radiation includes consideration of many factors, such as: balancing of societal interests, technical feasibility, cost-benefit analysis, value analysis, alternative actions, quantification of potential health effects, probabilities and ranges of uncertainty for exposures and for over-all-risk evaluations for individuals and for population groups. These factors, which in past years were only considered qualitatively (if at all), are responsive to the evolutionary trend of public health protection toward a contemporary philosophy eliminating unnecessary hazards and keeping levels of exposure and risks "as low as reasonably achievable."

RESOURCES FOR RADIATION RESEARCH AND REGULATORY PROGRAMS

Most of the Nuclear Regulatory Commission's resources are dedicated to assuring that there will be no undue risks to the health and safety of the public from licensed nuclear activities. Taking this broad view that substantially all NRC efforts are related directly or indirectly to radiation programs, that is, the purpose of the regulatory program is to reduce or to prevent exposures to radiation in routine operations and in potential accident or sabotage situations, then the NRC manpower and other resources spent on "radiation research and regulatory programs," the terms used by the Committee, would be close to correspond to the total NRC budget. The total budgets for the years since NRC was formed in 1975, to date, are:

1975:	
Persons	2, 006
Amount (millions)	$148
1976:	
Persons	2, 289
Amount (millions)	$222
1977:	
Persons	2, 529
Amount (millions)	$256
1978:	
Persons	2, 695
Amount (millions)	$292

These annual budget totals are subdivided in Table 1 according to NRC functional activities.

However, some of the NRC effort is in consideration of nonradiological environmental issues, such as socioeconomic impacts and chemical and thermal discharges, or anti-trust considerations. We have attempted to subtract resources used in such efforts and to use the format suggested by the Committee in their correspondence to us. Table 2 presents resource expenditures adjusted in such a manner for the principally involved offices of NRC, namely Nuclear Reactor Regulation, Nuclear Materials Safety and Safeguards, Nuclear Regulatory Research, Inspection and Enforcement, State Programs and Standards Development.

TABLE 1.—NRC ANNUAL BUDGET AND AUTHORIZED MANPOWER, 1975–78

[Dollar amounts in millions]

	1975		1976		1977		1978	
	Persons	Amount	Persons	Amount	Persons	Amount	Persons	Amount
Powerplant licensing	583	$31.4	595	$35.5	612	$40.4	618	$40.0
Program direction and administration	447	13.2	536	23.3	549	23.8	583	29.3
Standards development	112	6.8	130	9.8	151	11.8	153	12.1
Inspection and enforcement	419	16.6	506	21.8	592	28.7	666	30.1
Material safety and safeguards	152	3.7	190	12.9	263	18.7	284	22.1
Research	94	68.8	117	109.0	137	121.9	150	148.4
ACRS, boards and legal	199	7.5	215	9.8	225	10.8	241	10.2
Total	2,006	148.0	2,289	222.0	2,529	256.0	2,695	292.0

TABLE 2 NRC MANPOWER AND RESOURCES EXPENDED ON REGULATORY RADIATION PROGRAMS AND RADIATION RESEARCH

Ionizing Radiation

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Animal/ Plant	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or Analysis of Health Data	Collection and/or analysis of environmntl data	Reactor Safety Research & Fuel Cycle Research	Environ. Surveys and Generic & Spec. Studies
1975 P	--	--	--	131	25	1083	--	4	--	--	--	20
$M	--	--	--	$3.43	$0.12	$15.4	$0.18	0	--	--	--	0
$\$M^1$	--	--	--	$7.29	$0.42	$52.7	$0.18	$0.05	--	--	--	$0.24
1976 P	0.5	0.3	0.3	168	25	1214	--	4	0.5	0.5	93	21
$M	$0.61	$0.77	$0.27	$6.50	$0.22	$17.8	$0.20	0	$ .74	$1.46	$86.9	$2.19
$\$M^1$	$0.77	$0.92	$0.42	$12.23	$1.02	$63.0	$0.20	$0.13	$0.90	$1.62	$89.9	$2.86
1977 P	0.5	0.5	0.5	207	19	1345	--	5	0.5	1	108	17
$M	$0.51	$0.54	$0.35	$8.97	$0.42	$22.5	$0.20	0	$0.93	$1.29	$108.1	$0.56
$\$M^1$	$0.66	$0.69	$0.51	$17.28	$1.12	$79.2	$0.20	$0.19	$1.09	$1.61	$112.1	$1.20
1978 P	0.5	0.5	0.5	213	24	1602	--	5	0.5	1	123	11
$M	$0.45	$0.57	$0.40	$9.24	$0.67	$26.0	$0.22	0	$0.45	$1.31	$132.8	$1.0
$\$M^1$	$0.61	$0.73	$0.56	$16.58	$1.59	$82.0	$0.22	$0.20	$0.61	$1.62	$137.6	$1.43

P = NRC manpower in number of persons
$M = NRC resources spent outside NRC in millions of dollars
$\$M^1$= Total NRC resources spent in millions of dollars

Question 1. What changes in your jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Response. On January 19, 1975, the U.S. Nuclear Regulatory Commission, established pursuant to section 201 of the Energy Reorganization Act of 1974, as amended,[1] assumed the licensing and related regulatory functions vested in the former U.S. Atomic Energy Commission by the provisions of the Atomic Energy Act of 1954, as amended.[2] A major objective of the Energy Reorganization Act of 1974, which became law October 11, 1974 and went into effect January 19, 1975, was to separate the developmental and promotional responsibilities of the Atomic Energy Commission from its licensing and related regulatory functions. The Act abolished the Atomic Energy Commission and established two new agencies in its place—the Energy Research and Development Administration, a new independent executive agency, and the Nuclear Regulatory Commission, a new independent regulatory commission. In addition to assuming the licensing and related regulatory responsibilities of the former AEC, the NRC was also given express authority to license and regulate certain ERDA activities.[3]

The regulatory jurisdiction of the NRC is basically the same as that of the former Atomic Energy Commission which has remained substantially unchanged since 1954.[4] Thus, the statutory mission of the Nuclear Regulatory Commission is to regulate civilian nuclear energy activities to ensure that they are conducted in a manner which will protect the public from the standpoint of radiological health and safety, maintain national security and comply with the antitrust laws. (Following the enactment of the National Environmental Policy Act of 1969, the Commission was charged with the responsibility of carrying out these functions in a manner which will protect the environment). To this end, the Commission is empowered to license and regulate utilization and production facilities (e.g., nuclear power plants and fuel reprocessing plants), source material (e.g., uranium and thorium), byproduct material (e.g., radioisotopes), and special nuclear material (e.g., plutonium and enriched uranium), and certain activities of the Energy Research and Development Administration. The Commission's regulatory authority does not extend to naturally occurring radioactive materials (other than source materials) such as radium or to accelerator-produced radioactive materials.

Although the Commission's jurisdiction has remained substantially the same, except for the transfer to EPA under Reorganization Plan No. 3 of 1970 of certain functions of the former Atomic Energy Commission respecting the establishment of "generally applicable environmental standards for the protection of the general environment from radioactive material," [5] amendments to the Atomic Energy Act, both prior to 1968 and during the period 1968–1977 and the enactment of new laws, principally laws designed to protect the environment, have changed the manner in which the Commission has exercised its basic authority and the matters which it must consider in carrying out its regulatory responsibilities.

Two examples of amendments to the Atomic Energy Act which have altered the Commission's responsibilities are: Public Law 91–161, December 24, 1969, 83 Stat. 444, which added a new section 234 to the Atomic Energy Act of 1954, as amended, authorizing The Commission, in addition to, or in lieu of, taking administrative action such as suspending or revoking a license or issuing a cease and desist order, to impose civil monetary penalties on persons who violate the licensing provisions of the Act or any rule, regulation, order or license issued thereunder. This added authority was designed to give the Commission more flexibility in dealing with infractions of varying severity.

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[1] Pub. Law 93–438, 88 Stat. 1233 at 1242, as amended by Pub. Law 94–79, 89 Stat. 413–414 (42 U.S.C. 5841), Executive Order 11834, dated January 15, 1975, 40 FR 2871, January 17, 1975.

[2] Pub. Law 83–703, as amended, 68 Stat. 919 (42 U.S.C. Ch. 23).

[3] Sec. 202, Energy Reorganization Act of 1974, 88 Stat. 1244, 42 U.S.C.A. § 5842.

[4] The Atomic Energy Act of 1954, which amended the earlier Atomic Energy Act of 1946, was enacted to provide a legal framework within which government and industry could work together to develop and promote and the government would regulate the industrial and commercial uses of atomic energy for peaceful purposes. These uses included the construction and operation of nuclear power plants and the use of byproduct material and special nuclear material in various forms and devices for industrial and medical purposes.

[5] Reorganization Plan No. 3 of 1970, effective Dec. 2, 1970, 35 FR 15623, 84 Stat. 2086, 5 U.S.C.A. Appendix II Reorganization Plans, 1977 Cumulative Annual Pocket Part. See Attachment A, pp. 6–9 for a detailed discussion of this transfer.

Public Law 91–560, December 19, 1970, 84 Stat. 1472, which amended the Atomic Energy Act of 1954, as amended, to eliminate the requirement for finding of "practical value" by the AEC before nuclear facilities (such as power reactors and fuel reprocessing plants) can be licensed under the "commercial section" (section 103) of the Act. The principal effect of this change was to subject applications for section 103 facility licenses to pre-licensing antitrust review by the Attorney General and the Commission. Consistent with this change, Public Law 91–560 amended the provisions of section 191a of the Act which prescribe the qualifications of members of Atomic Safety and Licensing Boards to permit the Commission to appoint as Board members persons with expertise appropriate to the issues to be decided. In addition, the general notice provision (section 182c) was amended to assure that various regulatory agencies and others received adequate notice of the application.

In addition, the Commission's exercise of its authority has also been affected by the 1975 amendment of section 201 of the Energy Reorganization Act of 1974.

In 1975, Congress amended section 201 of the Energy Reorganization Act of 1974 (Public Law 94–79, August 9, 1975, 89 Stat. 413–414) which, in addition to providing that the Chairman of the Commission shall serve as its principal executive officer and clarifying certain provisions relating to the terms of the Commissioners, also included the following provision:

"The Nuclear Regulatory Commission shall not license any shipments by air transport of plutonium in any form whether exports, imports or domestic shipments: *Provided, however*, That any plutonium in any form contained in a medical device designed for individual human application is not subject to this restriction. This restriction shall be in force until the Nuclear Regulatory Commission has certified to the Joint Committee on Atomic Energy of the Congress that a safe container has been developed and tested which will not rupture under crash and blast-testing equivalent to the crash and explosion of a high-flying aircraft."

On August 15, 1975, the Commission's Office of Nuclear Material Safety and Safeguards issued an order stopping the shipment of plutonium by air. Since that time the Commission has been engaged in developing a safe container which can be certified to the Joint Committee as meeting the statutory requirements. Attachment A contains a detailed discussion of the way in which the Commission's jurisdictional responsibilities have been affected during the period from 1968–1977 by the National Environmental Policy Act of 1969 and by authority exercised by other Federal agencies in the areas of environmental protection, transportation, nuclear medicine and in connection with the regulation of floating nuclear power plants and nuclear power electric generating stations located on coastal and inland navigable waters. The authorities vested in the Secretary of the Department of Health, Education, and Welfare under the Radiation Control for Health and Safety Act of 1968, which is concerned with radiation caused by the operation of an electronic circuit, have not impinged on the Commission's licensing and related regulatory function.[6]

As indicated above and as described more fully in Attachment A, the Nuclear Regulatory Commission has accommodated changes in jurisdiction and the impacts of other laws on its regulatory authority in a number of ways, including negotiation and execution of formal Memoranda of Understanding, participation on interagency committees and in the interagency comment process, changes in NRC regulations and licenses, and use of informal cooperative procedures.

Question 2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with State agencies? Is there any confusion concerning respective responsibilities of State and Federal agencies?

Response. The Commission recognizes that the States have a growing interest in the work of our agency and are playing an increasingly important role in our regulatory process. In July 1976, the Commission established a separate Office of State Programs (OSP) with responsibility for improving and enhancing our relations with the States. The OSP is charged with certain aspects of our agency's emergency preparedness efforts, the supervision of the Agreement States program and certain of the other programs mentioned below.

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[6] Section 4 of the Radiation Control for Health and Safety Act states that "The amendments made by section 2 of this Act shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States."

In addition, under section 274 of the Atomic Energy Act, the Commission is authorized to enter into agreements with States by which they assume regulatory responsibility for certain kinds, quantities, and uses of radioactive materials. Twenty-five Agreement States now administer over 55% of the effective licenses in the United States. The Commission is currently reexamining this program with a view to assuring effective Federal standards and broad State participation, as well as possibly increased areas of State responsibility. The Commission expects to have the results of this study available within the next few weeks.

On March 24, 1977, the Chairman of NRC wrote to each State Governor and requested their candid and direct views on whether the present arrangement under the Atomic Energy Act of 1954, as amended, of exclusive Federal control over radiation health and safety requires revision and, if so, what form should changes take. Of the twenty responses received to date, fourteen Governors said that no changes in the current regulatory scheme were necessary. Reasons cited for continuing Federal control are the complex nature of the facilities and the financial burden of establishing a competent technical review organization at the State level.

Two Governors (Oregon and Arkansas) indicated that the Federal government should act as a coordinator of State activities, set standards and establish an Agreement State concept for monitoring and enforcement authority around nuclear facilities. The Governors of Connecticut and Michigan indicated that the States needed to play a more meaningful role and that Federal and State agencies should share decisions. The Governor of Kentucky supports the view that the Federal government should own low-level burial facilities and they should be regulated jointly by the State and Federal governments. Additionally, he suggests that Federal regulation be extended to include the use of radioactive materials which are not presently covered by the Atomic Energy Act.

A number of Governors state strong support for the continuation of the Agreement State Program whereby the Commission relinquishes regulatory authority over source, byproduct and small quantities of special nuclear materials to the States.

General opinion favors early notification to a State and neighboring States of the possible location of a nuclear facility within a State. All information concerning application for license made to NRC should be made available to the State with sufficient opportunity for State discussions with the NRC and with the applicant.

No State indicated the necessity for a State to decide on the radiological safety of a particular facility. The general consensus apparently is that the States want to be involved in the process to assure themselves and their citizens that the Federal performance meets the needs of the States.

Of particular interest to the Governors was the States' role in planning for energy development. Nine Governors indicated that States should make the decisions on siting need for power, land use, and the social and physical environment. South Dakota suggested that a State's "need for power" determination should be binding on the Federal Government.

One Governor (Montana) recommended that the Atomic Energy Act be amended to allow States to impose more stringent radiological effluent standards than those established by the Federal Government.

These suggestions are being addressed in ongoing staff studies at NRC.

The Commission has also directed its staff to study means to increase effectiveness in the siting of nuclear facilities. The study has now been released by the Commission as a preliminary staff statement. The statement is titled: "Improving Regulatory Effectiveness in Federal/State Siting Actions", May 1977, Report No. NUREG 0195. The statement makes five important recommendations aimed at improving the coordination of Federal reviews.

1. That Federal legislation authorize coordinated early and open planning by utilities and States or associations of States for all forms of electrical generation.
2. That the National Environmental Policy Act of 1969 be amended to allow Federal agencies to accept for inclusion in final environmental impact statements environmental reviews performed by qualified States acting under carefully constructed Federal guidelines.
3. That States be authorized to certify sites for generating facilities.
4. That State certification of need for power (facility) be final and binding on Federal agencies.

5. That coordination of Federal and State regulatory actions be emphasized in order to minimize duplication and create a commonly available data base.

Attachment B[1] is a copy of the Executive Summary from NUREG 0195.

On a related matter, the Commission has increased its emphasis on the conduct of joint hearings with States with respect to matters to concurrent jurisdiction. First initiated in Maryland, his process is now underway in New York State, and, recently, Massachusetts has requested joint hearing on a pending license. The Commission hopes to make this approach widely known to the States. In a similar way, the Commission has been encouraging the development of understandings with States to promote more efficient discharge of mutual responsibilities.

Several other items are worthy of note: the Commission provides training to State and local officials in radiological health and safety matters, as well as in preparedness for radiation emergencies. It also provides assistance and technical support to States in responding to radiological incidents. As a matter of routine, NRC regional offices promptly notify the States of significant or unusual events involving NRC-licensed facilities or activities within their borders. The Commission supports through contracts the Conference of (State) Radiation Control Program Directors, and NRC has a number of cooperative arrangements with States where reactors are located for environmental radiation monitoring and also has data collection contractual agreements in some of the States. Also, in conjunction with the Department of Transportation, the Commission has developed a three-year cost sharing program to help States monitor the transport of low-level radioactive material within their borders. Since 1975, the Commission has been working with State geology agencies to develop regional seismotectonic maps, an important aspect of future plans to standardize the Commission's approach to seismic risk assessment in the Eastern United States.

The Commission has also encouraged the States to appoint liaison officers to deal with the Commission on a day-to-day basis, particularly in the area of our non-radiological environmental review process. To date, twenty-four Governors have made such appointments. The Commission has also instituted a long-range study on the feasibility of assigning various Commission functions to our regional offices and. as a first step, the Commission decided on a pilot program to place State liaison officers in some or all of NRC's five regional offices.

We have a continuing joint activity we are engaged in with the Bureau of Radiological Health and the Conference of Radiation Control Program Director for the development and updating of suggested State Regulations which provide a framework for the control of radioctive materials and also radiation producing machines. A number of States, both NRC Agreement States and some non-Agreement States, make use of these suggested regulations.

In response to requests from the Conference of Radiation Control Program Directors and from the Agreement States, the NRC formed a Task Force to review the matter of regulation of naturally occurring and accelerator produced radioactive materials. Such radioactive materials are not now subject to NRC licensing and regulation. The Task Force's work is nearing completion and a report expected to be available in the near future.

Recently, the NRC published effective rules establishing procedures for early site review of proposed nuclear reactor power stations (42 FR No. 87, 22882–22888 May 5, 1977, effective June 6, 1977). Some States originally had expressed concern that State regulatory processes would be adversely affected. In response to these concerns, the Commission made substantial changes in the effective regulation to encourage State and local government participation in early site review proceedings. It is the Commission's intent to consider carefully the needs and desires of State and local officials in the actions taken under the early site review rule.

Some of the NRC/State power plant site evalution efforts address regional issues. In one such effort currently underway in the Southeastern States a long-range utility energy facility siting project is being studied as a possible regional siting demonstration project, and mechanisms are in place to ensure early public involvement along with coordinated Federal, regional, and State site reviews.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved? Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

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[1] Attachment B is in the committee files.

Response. Regulation of activities pursuant to the Atomic Energy Act is, appropriately, the responsibility of the NRC, in some areas delegated to the 25 Agreement States. In the past, there has been some uncertainty regarding the authorities and responsiblities of EPA and NRC in establishing the radiation standards within which this regulation occurs. Occasionally this has led to confusion which has the potential for duplication of efforts or for contradictory requirements.

In developing sound and workable standards, the NRC must work effectively with many groups, both within and outside Government. In this regard, the Commission places particular emphasis on coordinating the development of environment standards, particularly radiation standards, with the Environmental Protection Agency and other concerned parties.

The funding levels for the regulation of radiation programs and research conducted by NRC pursuant to the Atomic Energy Act and the Energy Reorganization Act and approved by Congress on a yearly basis are adequate.

Question 4. What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal radiation agency?

Response. The term "radiation activities" covers Federal programs now divided among several agencies. For example, the Food and Drug Administration, because of its particular expertise in the medical applications of X-rays, regulates X-ray devices; the Environmental Protection Agency sets standards of general applicability pertaining to radiation; and NRC regulates radiation health and safety issues pertaining to activities, facilities, and materials under the Atomic Energy Act of 1954 and the Energy Reorganization Act.

We believe that some consolidation of Federal radiation activities could result in a reduction of duplication, particularly in the area of the authorities and responsibilities of EPA and NRC, as we mentioned in our response to question 3. The greatest potential overlap is with EPA's standards-setting activities, where the need for coordination is appreciated by both agencies and was treated explicitly in Reorganization Plan No. 3 of 1970. Other limited aspects of NRC jurisdiction have from time to time been duplicated in other agencies, both Federal and State, but the Supreme Court has recently reaffirmed NRC's preemptive regulatory authority under the Atomic Energy Act over radiological health and safety aspects of nuclear generating facilities. *Train* v. *Colorado Public Interest Research Group*, 426 U.S. 1 (1976).

The Environmental Protection Agency, in exercise of the authority of the Federal Radiation Council, can assure uniformity of approach and balance in the field of radiation protection. Under this authority EPA can develop Federal radiation guidance for promulgation by the President. We understand that development work of this sort is being contemplated or is already underway in several areas.

Consideration of the question of adjustments of authority within the Federal government could also appropriately consider the important related issue of adjustments in regulatory authority between the Federal government and the States. Some of these issues will be discussed in the forthcoming "Task Force Report on Naturally Occurring and Accelerator Produced Radioactive Materials" referred to in our response to question No. 2, above.

It is essential, of course, that any reorganization be carefully structured so as to assure that in the interests of greater efficiency, changes are not made which result in a diminution of protection to the public in these extremely important areas. It must be recognized that the diversity of the sources and uses of radiation—from microwave ovens in the home to nuclear powerplants—requires varying regulatory treatment, whether regulation is assigned to one agency or several.

NRC would appreciate the opportunity to address the merits of any consolidation which may be proposed.

ATTACHMENT A

EXERCISE OF NRC JURISDICTION

I. ENVIRONMENTAL PROTECTION

A. NEPA-RELATED STATUTORY AUTHORITIES

Pursuant to the provisions of the National Environmental Policy Act of 1969 (NEPA), the Nuclear Regulatory Commission is required to carry out its licensing and related regulatory responsibilities in a manner which will protect and enhance the environment. Specifically, the Commission is required, in accordance with the environmental impact statement procedures prescribed by section 102(2)(C) of NEPA (42 U.S.C. 4332), to evaluate the environmental impacts of each proposed major action and the available alternative actions and, to determine, on the basis of an analysis which considers and balances the environmental effects of the facility, the alternatives available for reducing or avoiding adverse environmental effects, and economic, technical and other costs and benefits, whether a license or permit for a nuclear power plant or other facility or activity should be issued, denied or issued with conditions designed to mitigate undesirable environmental effects.

In carrying out its responsibilities under NEPA, the Commission has become aware of certain areas in which its responsibilities impinge on those of other Federal agencies. In these areas of common concern, the broad environmental review responsibilities vested in NRC by NEPA overlap with other more specific environmental review responsibilities related to nuclear activities vested in other Federal agencies—e.g., The Federal Water Pollution Control Act, as amended, Coastal Zone Management Act of 1972, Wild and Scenic Rivers Act, National Historic Preservation Act, Endangered Species Conservation Act, Fish and Wildlife Coordination Act. At present, these overlaps are most substantial in connection with implementation of the Federal Water Pollution Control Act Amendments of 1972. These overlaps could be substantial in connection with the implementation of the Coastal Zone Management Act.

1. The Federal Water Pollution Control Act Amendments of 1972 (hereafter referred to as FWPCA), Public Law 92–500, October 18, 1972, 86 Stat. 816 et seq.

Background.—Prior to the enactment of the National Environmental Policy Act of 1969 (NEPA), Federal and State agencies other than the Atomic Energy Commission (NRC's predecessor) exercised control over the discharge of nonradiological pollutants, such as heat, from nuclear power plants. Following the enactment of NEPA and the Water Quality Improvement Act of 1970, but prior to the enactment of the 1972 amendments to the Federal Water Pollution Control Act, AEC was precluded from issuing construction permits for nuclear power plants until a water quality certificate from the state in which the proposed facility was to be located was furnished (33 U.S.C. 1171(b)). This certificate, known as a "21(b) certificate" after the section of the Federal Water Pollution Control Act which established the need for it, had to indicate that there was "reasonable assurance" that the discharges from the facility would not violate the State's water quality standards. In addition to insuring that such a certificate was obtained, AEC understood its obligations under NEPA to require that it make an independent appraisal of the impact of the discharge on water quality, implement any cooling system alternatives that could, at a favorable cost-benefit balance, reduce the impact of the discharge, and consider any residual adverse environmental impact in the overall cost-benefit balance.

The Federal Water Pollution Control Act Amendments of 1972 expanded the role of the Environmental Protection Agency with respect to the protection of water quality. At the same time, in furtherance of a policy of reducing "needless duplication and unnecessary delays at all levels of government"[1] it significantly reduced the scope of the obligations otherwise assigned to the Commission under NEPA (sec. 511(c)(2), FWPCA, 33 U.S.C. 1371(c)(2)).

Pursuant to section 402 of the FWPCA (33 U.S.C. 1342), EPA is authorized to issue a permit allowing the discharge of a pollutant if the discharge complies with certain standards established by the provisions of the FWPCA. (See e.g., secs. 301, 302, 306, 307, 308, 316, 403, 33 U.S.C. 1311, 1312, 1316, 1317, 1318, 1326, 1343.) Heat and chemical wastes are discharged from nuclear power plants and are considered pollutants within the meaning of the FWPCA (33 U.S.C. 1362(b)). However, pursuant to the opinion of the U.S. Supreme Court in *Train* v. *Colorado Public Interest Research Group, Inc.*, 426 U.S. 1, June 1, 1976, source, byproduct and special nuclear materials regulated by NRC are not pollutants within the meaning of the FWPCA.

The Federal Water Pollution Control Act Amendments of 1972 changed the role of the former Atomic Energy Commission (now exercised by the Nuclear Regulatory Commission) in this regulatory scheme. Instead of the prior requirement that NRC obtain a state certification of reasonable assurance that state water quality standards will be met, NRC is now required to obtain a state certification (sec. 401, FWPCA, 33 U.S.C. 1341) that the proposed discharge will comply with Federal standards, i.e., with certain applicable provisions, such as section 301, of FWPCA. Certain requirements and limitations contained in this certificate must be included as conditions in the NRC permit or license. If the requisite certificate is denied, NRC is prohibited by section 401, as it was also prohibited by sec. 21(b), from issuing a permit or license. Section 511 of the FWPCA (33 U.S.C. 1371) explicitly provides that nothing under NEPA shall be deemed to authorize any Federal agency to review any effluent limitation or other requirement established pursuant to the FWPCA, or to impose, as a condition of any license or permit, any effluent limitation other than any such limitation established pursuant to the FWPCA.

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[1] Sec. 101(f), FWPCA, 33 U.S.C. 1251(f).

These statutory changes have altered the nature of NRC's NEPA review. Instead of specifying requirements for inclusion in permits and licenses to minimize aquatic environmental impacts from nuclear power reactors, NRC's role is confined to evaluating, as one factor in the overall cost-benefit balance prescribed by NEPA, the environmental impacts of nuclear facilities on water quality assuming EPA standards and requirements have been met. Thus, both NRC and EPA (or permitting States under sec. 402 of the FWPCA, 33 U.S.C. 1342) must evaluate water pollution impacts, but EPA and the States have the preeminent role in setting and enforcing water pollution standards and limitations.

For the system to work to maximum advantage, it is necessary for EPA to have made its determination relative to a nuclear power plant's cooling system in advance of NRC's consideration of the matter. The close interface between the respective statutory authority of EPA and NRC in the area of water quality and the resultant problems of implementation led NRC and EPA on December 17, 1975 to enter into a Second Memorandum of Understanding to clarify their respective roles in the decision-making process concerning nuclear power plants and other facilities requiring an NRC license or permit. A copy of this Second Memorandum of Understanding, which became effective January 30, 1976, is attached. (Second Memorandum of Understanding is available in committee files.)

The purpose of the Second Memorandum of Understanding is to reduce demands for water quality data placed on applicants for nuclear facilities by assuring that applicants' environmental reports contain sufficient information to meet both NRC's needs under NEPA and EPA's needs under the FWPCA, and to minimize any duplication of effort between NRC and EPA in meeting their respective responsibilities under NEPA and the FWPCA.

The Second Memorandum of Understanding provides, among other things, that:

> NRC is to serve as the lead agency for preparation of environmental impact statements for nuclear facilities;
>
> NRC and EPA will cooperate in identifying and consolidating their respective requirements under NEPA and FWPCA for water quality data;
>
> EPA will participate with NRC in the evaluation of water quality impacts;
>
> In those states which do not have NPDES permitting authority, EPA will issue NPDES section 402 permits, section 316(a) exemptions and section 316(b) analyses of intake structures "as far as possible in advance" of the date of issuance by NRC of its final environmental impact statement; (Emphasis supplied.)
>
> NRC and EPA will consider the feasibility of holding joint or concurrent hearings.

Circumstances in which EPA's FWPCA responsibilities and NRC's NEPA responsibilities are most likely to cause difficulties are those in which EPA's FWPCA requirements with respect to a particular nuclear facility (the need for cooling towers or the location of water intake structures, for example) have not been finally determined. In those instances in which a proposed applicant is seeking a section 316(a) exemption from EPA, any uncertainty as to the final disposition of the applicant's request before EPA can have a significant impact on both the scope and outcome of NRC's NEPA review, since it is possible that in some cases NRC may be unable to complete its NEPA review without knowledge of the requirements to be imposed under FWPCA. In at least one case, uncertainty as to final action on a section 402 discharge permit has had a substantial impact on the Commission's licensing process.

2. *Coastal Zone Management Act of 1972 as amended, Pub. Law 92–583, October 27, 1972, 86 Stat. 1280, 16 U.S.C.A. §§ 1451, et seq.*

The Coastal Zone Management Act of 1972, as amended, establishes a statutory scheme, under which states are encouraged, with Federal assistance, to develop and implement coastal zone management programs which will achieve wise use of the land and water resources of the coastal zone giving full consideration to ecological, cultural, historic, and esthetic values as well as the need for economic development. State coastal zone management programs are required to include a "planning process for energy facilities likely to be located in, or which may significantly affect, the coastal zone, including but not limited to, a process for anticipating and managing the impacts from such facilities." The term "energy facilities", as defined in the Act, includes electric generating plants (nuclear power reactors fall in this category) and uranium enrichment and nuclear fuel processing facilities. These facilities are subject to regulation by NRC.

In passing the Coastal Zone Management Act, Congress included a provision (usually referred to as the "FEDERAL CONSISTENCY" provision, Section 307, as amended, 16 U.S.C.A. § 1456) to encourage states to enter into the program and to promote comprehensive Federal-State cooperative coastal zone land and water use management. Generally, the provision requires Federal agencies to administer their direct activities, regulatory functions, and assistance programs in a manner consistent with approved state coastal management programs. Pursuant to subsection (c)(3)(A) of section 307 (16 U.S.C.A. 1456(c)(3)(A)), any applicant for a required Federal license or permit to conduct an activity affecting land or water uses in the coastal zone of a state with an approved coastal zone management program shall provide in his application for a federal permit or license ". . . a certification that the proposed activity complies with the state's approved program and that such activity will be conducted in a manner consistent with the program. . . ."

This subsection also provides that: "No license or permit shall be granted by the Federal agency until the state or its designated agency has concurred with the applicant's certification or until, by the state's failure to act, the concurrence is conclusively presumed, unless the Secretary, on his own initiative or upon appeal by the applicant, finds, after providing a reasonable opportunity for detailed comments from the Federal agency involved and from the state, that the activity is consistent with the objectives of this chapter or is otherwise necessary in the interest of national security."

The national coastal zone management program has now reached the stage where a number of states are completing development of their management programs and will be seeking the requisite approval of those programs which must be obtained in order to trigger the requirements of the Federal Consistency provision. The Department of Commerce is currently engaged in developing proposed regulations to be issued for public comment to implement that provision.

Although it is still too early to evaluate the workability of the Federal Consistency provision and its impact on NRC's regulatory program, indications are that the certification and state concurrence requirements of section 307(c)(3)(A) could become an important factor in NRC's grant of construction permits and licenses for facilities which are either located in coastal zones or are located in areas outside of but affecting coastal zones. Under NEPA, NRC would be required to independently evaluate coastal zone impacts, notwithstanding the approval of the proposed license by the State and/or Secretary.

B. RADIOLOGICAL-RELATED STATUTORY AUTHORITIES

1. *Authority transferred to EPA by Reorganization Plan No. 3 of 1970 to carry out*

(a) Certain functions of the former Atomic Energy Commisison respecting the establishment of "generally applicable environmental standards for the protection of the general environment from radioactive material."

(b) All functions of the Federal Radiation Council.

(*a*) *Transferred functions relating to generally applicable environmental radiation standards*

The functions transferred from the former AEC respecting the establishment of generally applicable environmental standards were those administered by the AEC's Division of Radiation Protection Standards. These standard-setting functions involved the establishment of ambient standards, i.e., limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

In the message to Congress transmitting Reorganization Plan No. 3 of 1970, the President stated that "AEC would retain responsibility for the implementation and enforcement of radiation standards through its licensing authority."

Recognizing their complementary responsibilities in the areas of environmental protection and the control of radiation effects occasioned by this transfer of functions, EPA and the former AEC executed a Memorandum of Understanding with respect to AEC-Licensed Facilities in August 1973. The purpose of this Memorandum of Understanding (copy attached)[1] was "to fix an appropriate interface of the respective functions of the two agencies, to further facilitate their useful cooperation, and to avoid unnecessary duplication of regulatory effort, . . ."

On January 13, 1977, pursuant to its transferred authority to set generally applicable environmental standards, EPA published a new Part 190 to its regulations (40 CFR Part 190—Environmental Radiation Protection Standards for Nuclear Power Operations; 42 FR 2858–2861) establishing environmental radiation protection standards for the uranium fuel cycle. These standards specify levels below which normal operations of the uranium fuel cycle are determined to be environmentally acceptable.

In the statement of considerations which accompanied the rule, EPA stated that "[t]he authority to regulate fuel cycle facilities under these standards resides in the Nuclear Regulatory Commission . . ." EPA also pointed out that "[i]n situations where members of the public are actually exposed, these standards, [40 CFR Part 190] in effect, preempt those regulations which are based upon the Federal Radiation Protection Guides (25 FR 4402) insofar as exposure of the public is due to operations defined to be included in the uranium fuel cycle. For example, the dose limits in 10 CFR Part 20 [NRC regulations establishing standards for protection against radiation hazards arising out of activities under licenses issued by NRC] would not be the limiting consideration regarding exposure of members of the public as a result of uranium fuel cycle operations. . . ."

As contemplated by the provisions of the 1973 Memorandum of Understanding, NRC staff has recently established a task group to prepare recommendations for Commission consideration on the regulatory changes which will be needed to implement EPA's Uranium Fuel Cycle Standard. In theory, there will be no conflict between NRC's and EPA's responsibilities under the Atomic Energy Act since NRC is obligated to enforce the EPA general standards. However, the precise limits of EPA's general standard-setting authority are uncertain. In this "gray area" there is a potential for confusion and overlap. In the uranium fuel cycle area, the limits of authority are now defined. In the nuclear waste management area, the precise limits are as yet to be defined.

On December 6, 1976, EPA published an Advance Notice of Proposed Rulemaking (41 FR 53363) in which it announced its intent to develop environmental radiation protection standards for high-level radioactive wastes to assure protection of the public health and the general environment from these wastes. In its notice, EPA stated that it intended to develop applicable environmental criteria for all radioactive wastes and that in the development of these criteria and standards it would consider all currently available information on long-term implications of radioactive wastes and the risks associated with such wastes. The EPA notice announced that the subject would be discussed in depth at a series of workshops and requested pertinent information respecting the following matters:

> The capability of various types of source encapsulation to retain high activity wastes or long-lived alpha wastes for long periods.
>
> The geologic media that may be used to contain high activity wastes, long-lived alpha wastes, or combined wastes and the retention capabilities of those media over long periods of time.
>
> Predictions of the most likely transfer co-efficients of radioactive material for selected combinations of source encapsulation, engineering containerization, geologic media, and predicted environmental levels for long periods of time.
>
> The probability and risks associated with accidental disturbances, either occurring naturally or as a result of institutional failures, and the impact of these risks on the predictions mentioned above.
>
> Factors important to providing reasonable assurance that environmental protection standards can be satisfied and that methods are available to implement environmental protection standards.

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[1] Available in committee files.

In the exercise of its statutory responsibilities for licensing and regulating nuclear power plants as well as other production and utilization facilities, for licensing and regulating certain ERDA facilities and for licensing and regulating special nuclear material, byproduct material and source material, NRC is actively engaged in developing criteria for use in licensing radioactive waste repositories which will assure that those repositories are constructed and operated in a manner which will preserve the common defense and security and protect the health and safety of the public. In connection with this regulatory program, NRC has underway a series of in-depth studies in many of the same areas in wihch EPA has announced its intent to conduct studies and investigations. In consequence, duplicative investigations which have a potential for yielding conflicting conclusions are currently in progress in the same substantive areas.

(*b*) *Transferred FRC functions*

The functions of the Federal Radiation Council as specified in its organic act[2] and transferred to the Environmental Protection Agency are to ". . . consult qualified scientists and experts in radiation matters, . . . and qualified experts in the field of biology and medicine and in the field of health physics. . . ." to ". . . advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. . . ." and to ". . . perform such other functions as the President may assign to it by Executive order. . . ." This statutory authority was designed to furnish a mechanism which would enable the President, on the basis of objective, independent advice reflecting the best scientific knowledge as well as policy considerations, to issue guidance to all Federal agencies which would assure uniformity and eliminate diversity in federal radiation standards. Although recommendations made by EPA in the exercise of this statutory authority are only advisory, once the President has approved these recommendations as guidance, it has generally been understood that federal agencies may not promulgate standards and regulations under their existing statutory authority which are inconsistent with that guidance.

Pursuant to its transferred FRC authority, EPA is engaged in reviewing Federal Radiation Protection Guides (25 FR 4402–4403, May 18, 1960) with a view to preparing revised recommendations for submission to the President for his approval and subsequent issuance as guidance to Federal agencies. In conducting these reviews, EPA has sought the counsel and advice of other Federal agencies, including NRC. At the present time, for example, a representative from NRC is serving on the Interagency Committee on Federal Guidance for Occupational Exposures to Ionizing Radiation established by EPA to develop recommendations on occupational radiation exposures. A representative from NRC is also serving on an Interagency Liaison Committee which is working with EPA to develop guidelines for the cleanup of plutonium and other transuranium elements and the restoration of contaminated areas. The objective of these guidelines is to set a level or levels of soil contamination above which cleanup is recommended. NRC, as well as other members of the Federal Interagency Central Coordinating Committee for Radiological Emergency Preparedness, has provided comments to EPA on proposed nuclear accident protective action guides for airborne release of radioactive gases and particulates. These Protective Action Guides are being prepared for use of Federal Agencies and States in emergency planning for accidents at fixed nuclear facilities and during transportation of nuclear materials. These interagency committees provide forums for the resolution of differences regarding the appropriate radiation standards. Following issuance of EPA recommendations as Presidential guidance, it is incumbent on NRC to review and amend its regulations as appropriate to bring them into conformity with this guidance. In this way, any potential conflict between NRC's regulatory authority and EPA's FRC authority to make recommendations regarding radiation standards is effectively resolved. However, in many cases both NRC and EPA would be authorized to conduct the same activities—NRC in the course of developing its own regulations (e.g., emergency preparedness requirements) and EPA in the course of developing guidance on radiation protection standards.

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[2] Public Law 86–373, 73 Stat. 688, 1959, Sec. 274h. of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2021(h).

On August 31, 1976, EPA published proposed regulations for State underground injection control programs (40 CFR Part 146; 41 FR 36730–36745, August 31, 1976). Although the statutory concepts of "underground injection" and "subsurface emplacement of fluids by well injection" were discussed at some length in the Federal Register notice, the issue of whether these concepts include emplacement below the surface of high-level or other radioactive wastes was not addressed.

2. *Safe Drinking Water Act, Public Law 93–523, December 16, 1974, 88 Stat. 1661, as amended, 42 U.S.C.A. §§ 300f–300j–9*

Part C of the Safe Drinking Water Act establishes a system of Federal-State controls to prevent underground injection which endangers drinking water sources. Under the provisions of the Act, State underground injection control programs must meet certain minimum requirements to secure federal approval, including the requirement that they prohibit any underground injection not authorized by State permit or State rule. The Act defines "underground injection" as the "subsurface emplacement of fluids by well injection." The Act further provides that underground injection shall be considered to endanger drinking water sources ". . . if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons." The term "contaminant" as used in the Act means "any physical, chemical, biological, or radiological substance or matter in water. . . ." Under this definition, special nuclear material, byproduct material and source material regulated by NRC would be considered contaminants. Whether there is a potential conflict between the provisions of the Atomic Energy Act of 1954, as amended, and the provisions of Part C of the Safe Drinking Water Act which authorize States to conduct underground injection permit programs depends on the manner in which the statutory definition of "underground injection" is interpreted. The potential scope of this defintion is rather broad and could conceivably include the emplacement below the surface of high-level or other radioactive wastes.

3. *Occupational Health and Safety*

In 1970, Congress enacted the Occupational Safety and Health Act of 1970 (Pub. L. 91–596, December 29, 1970, 84 Stat. 1590, 29 U.S.C. §§ 651 et seq.) to assure safe and healthful working conditions for working men and women. Section 4(b)(1) (29 U.S.C.A. § 653(b)(1)) of that Act states: "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

OSHA regulations specifically provide that employers who possess or use source material, byproduct material or special nuclear material under NRC or Agreement State licenses shall be deemed to be in compliance with OSHA regulations with respect to such possession and use (29 CFR § 1910.96(p).) Each year, NRC routinely makes a redetermination of continuing compatibility and adequacy of Agreement State regulatory programs. The U.S. Department of Labor has agreed to accept NRC's determination in lieu of their making independent investigations and determinations on safe working conditions for radiation workers in Agreement State licensee establishments under the Occupational Safety and Health Act of 1970.

Despite these procedures, uncertainty as to whether an overexposure in the workplace was occasioned by agreement materials (i.e., source material, byproduct material and special nuclear material in quantities not sufficient to form a critical mass) non-agreement sources of radiation or some combination of the two has resulted in the past in some overlapping in enforcement actions taken under State Agreements with the Nuclear Regulatory Commission and under OSHA-approved State plans. Following a meeting between NRC and OSHA staff members, an understanding was reached that violations arising from noncompliance with Agreement State radiation control regulations for agreement materials would be cited against the Agreement State radiation control regulations and violations of occupational safety and health standards for nonagreement sources of radiation would be cited under appropriate OSHA standards and procedures in those States which have OSHA approved State plans. A further u[illegible]rstanding was reached that citations would be predicated upon a determin[illegible]on of whether agreement materials or nonagreement sources of radiation were the major contributor to the violation.

II. FLOATING NUCLEAR POWER PLANTS AND NUCLEAR POWER ELECTRIC GENERATING STATIONS LOCATED ON COASTAL AND INLAND NAVIGABLE WATERS

A. U.S. COAST GUARD—NRC

On January 4, 1974, the former Atomic Energy Commission and the United States Coast Guard entered into a Memorandum of Understanding for the Regulation of Floating Nuclear Power Plants (39 FR 2124, January 17, 1974). (As defined in the Memorandum of Understanding a "floating nuclear power plant" is "a nuclear powerplant, mounted on and thereby integrally with a barge, fabricated at a central shipyard facility, then towed to a fixed position where it is installed and moored, nuclear fuel is loaded, and where it is operated as a floating facility to supply electrical energy into an onshore electrical load network.") The Memorandum of Understanding, which remains in effect and is adhere to by NRC, specifies detailed procedures under which the respective statutory responsibilitities of both agencies for the regulation of safety and protection of the environment from effects of construction and operation of floating nuclear power plants are to be exercised. (These statutory authorities are described in detail in section 2 of the Memorandum.) The Memorandum also identifies with particularity those aspects of floating nuclear power plants of primary concern to each agency and of joint concern to both agencies.

The purpose of the Memorandum, as stated herein, is to coordinate and implement consistent and comprehensive requirements to maximize safety with respect to the design, fabrication, construction and operation of floating nuclear power plants, to minimize the possible adverse environmental impact of such plants, and to minimize duplication and avoid possible inconsistency in safety requirements applied to such plants.

When the AEC and the U.S. Coast Guard began the negotiations which led to the preparation and execution of the Memorandum of Understanding, it was readily apparent that there were extensive areas of overlap and potential conflict with respect to their respective responsibilities for floating nuclear power plants. To date, NRC has found the Memorandum effective in achieving its objective of providing an orderly framework within which the regulatory responsibilities of the NRC and the U.S. Coast Guard with respect to floating nuclear power plants can be carried out in an efficient and consistent manner.

We would expect similar problems to arise in connection with the regulation of the construction and use of nuclear-powered merchant ships. NRC and the U.S. Coast Guard are presently engaged in discussions concerning memoranda of understanding to clarify their respective responsibilities in this area, including responsibilities relating to the presentaton of U.S. views regarding the safety of nuclear-powered merchant ships in such international forums as the Intergovernmental Maritime Consultative Organization (IMCO) and the Nuclear Energy Agency of the Organization for Economic Cooperation and Development (NEA/OECD).

B. U.S. ARMY CORPS OF ENGINEERS—NRC

Similar concerns regarding the impact of the regulatory authority of the U.S. Army Corps of Engineers over the construction of structures in navigable waters of the United States upon nuclear power electric generating stations, including floating nulear power plants, located on coastal and inland navigable waters and at offshore sites led the Nuclear Regulatory Commission and The Corps of Engineers to enter into a Memorandum of Understanding on July 2, 1975. (40 FR 37110, August 25, 1977. The purpose of this Memorandum of Understanding is to provide for the coordination and implementation of consistent and comprehensive requirements to assure effective, efficient and thorough regulation of nuclear power plants and to avoid conflicting and unnecessary duplication of effort and of standards related to overall public health and safety and environmental protection. The Memorandum details the relevant statutory authorities of each agency (sec. 2)[3] and describes the manner in which their respective responsibilities for issuing permits and licenses (sec. 4), taking enforcement actions (sec. 3), preparing environmental impact statements (sec. 3), conducting inspections (secs. 3b, 5d, e), reviews (sec. 5c, e), and public hearings (sec. 3c) will be carried out. Based on experience to date, NRC has found the procedures specified in the Memorandum effective in eliminating or minimizing areas of potential conflict between The Corps of Engineers and NRC and in enhancing the efficiency and effectiveness of their respective regulatory activities.

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[3] In the case of the U.S. Army Corps of Engineers, these statutory authorities include, among others, Section 404 of the Federal Water Pollution Control Act Amendments of 1972 and the Marine Protection, Research and Sanctuaries Act of 1972 which relates to ocean dumping.

III. TRANSPORTATION

Despite enactment of the Hazardous Materials Transportation Act in 1975, there has been little change since 1968 in the respective responsibilities of the U.S. Department of Transportation and the former Atomic Energy Commission (now the Nuclear Regulatory Commission) with respect to safety in the transportation of byproduct, source and special nuclear material on land in interstate and foreign commerce. As explained more fully herein, the continuing need to develop and implement consistent, comprehensive and effective regulations and to avoid duplication of effort led these agencies, on March 22, 1973, to enter into a revised Memorandum of Understanding which is presently in effect.

The licensing and related regulatory authority assumed by the U.S. Nuclear Regulatory Commission upon its establishment January 19, 1975 pursuant to section 201 of the Energy Reorganization Act, as amended[4], included authority to license and regulate[5], in a manner which will protect the environment[6], promote the common defense and security and protect the public from the standpoint of radiological health and safety, the receipt, possession, use and transfer, including packaging, shipment and transportation, of byproduct material, source material and special nuclear material as defined in sections 11e, z and aa of the Atomic Energy Act of 1954, as amended. (42 U.S.C. 2014(e), (z), (aa)).

Since most shipments of radioactive materials move in routine commerce on conventional transportation equipment and are subject to the same transportation environment, including accidents, as non-radioactive cargo, the NRC, in exercising its regulatory responsibilities under the Atomic Energy Act of 1954, as amended, has placed primary reliance on packaging to assure safety in transport. To make certain that only those shipments of radioactive materials which are safe enough to withstand transportation hazards without detriment to the health and safety of the public are delivered to a carrier for transport, the NRC has promulgated and continuously monitors compliance with detailed regulations pertaining to procedures and standards for packaging, labeling, and shipment of radioactive material (10 CFR Part 20, Standards for Protection Against Radiation, and Part 71, Packaging of Radioactive Material for Transport and Transportation of Radioactive Material under Certain Conditions). The NRC has also promulgated and monitors compliance with detailed regulations for the physical protection, including physical protection during transportation, of certain quantities of strategic special nuclear material (see generally 10 CFR Part 73, Physical Protection of Plants and Materials).

NRC safety standards for packages used in the transportation of radioactive materials (10 CFR Part 71) are applicable to packages used in all modes of transport. These standards and regulations are directed primarily towards assuring that packaging for radioactive materials is designed and constructed to maintain, under both normal and accident conditions over its useful lifetime, the necessary design integrity, considering the type, form and quantity of radioactive contents, to prevent a significant loss of radioactive material from a package or a significant increase in radiation levels from a package, to assure nuclear criticality safety, and to provide adequate heat removal. These standards reflect two basic considerations: (1) protection of the public from external radiation, and (2) assurance that either the radioactive contents of the package are unlikely to be released during normal or accident conditions of transport or, if the container is not designed to withstand accidents, the contents are so limited in quantity as to preclude a significant safety problem if released.

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[4] Pub. Law 93–438, 88 Stat. 1233 at 1242, as amended by Pub. Law 94–79, 89 Stat. 413–414 (42 U.S.C. 5841).

[5] See. for example, secs. 53, 57, 62, 63, 69 and 81 (42 U.S.C. 2073, 2077, 2092, 2093, 2099 and 2111) which authorize the issuance of licenses to, among other things, receive, possess and transfer special nuclear material, source material and byproduct material and sec. 161 (b) (42 U.S.C. 2201(b)) which authorizes the establishment "by rule, regulation or order [of] such standards and instructions to govern the possession and use of . . . [these materials] as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property."

[6] Pursuant to the National Environmental Policy Act of 1969, Pub. Law 91–190, 83 Stat. 852–856, 42 U.S.C. Ch. 55.

In addition to safety standards for packages, NRC regulations also include procedural controls applicable to the use of shipping containers. In particular, NRC regulations provide that NRC licensed materials may not be transported or delivered to a carrier for transport unless the licensee complies with applicable Department of Transportation (DOT) regulations and the shipment is authorized by a general or specific NRC license or is exempted from this license requirement by NRC regulations (10 CFR §§ 71.3, 71.5). Under the provisions of the general license contained in § 71.12 of NRC's regulations (10 CFR § 71.12) NRC licensed materials may be delivered to a carrier for transport in previously approved containers. NRC regulations also contain detailed procedures for opening and closing packages and for inspection of packages both before and after the first and each subsequent use (see generally 10 CFR § 20.205 and §§ 71.51–71.63).

Since its establishment in 1966, the U.S. Department of Transportation has had broad responsibility for transportation safety, including continuing and increasing authority to regulate the transportation of explosives, and other hazardous materials, including radioactive materials. This authority, which overlaps that of the Nuclear Regulatory Commission with respect to safety in the transportation of byproduct, source and special nuclear material on land in interstate and foreign commerce, is exercised pursuant to the Transportation of Explosives Act (18 U.S.C. 831–835), the Dangerous Cargo Act (R.S. 4472, as amended, 46 U.S.C. 170), Title VI and section 902(h) of the Federal Aviation Act of 1958 (49 U.S.C. 1421–1430 and 1472(h)) and most recently pursuant to the Transportation Safety Act of 1974, particularly Title I of that Act entitled the Hazardous Materials Transportation Act (49 U.S.C. 1801–1812). DOT authority includes authority formerly vested in the Interstate Commerce Commission under the provisions of the Transportation of Explosives Act which was expressly transferred to the Secretary of Transportation by Congress in 1966 (49 U.S.C. 1655(e)(4)).

Under the provisions of the Transportation of Explosives Act, which extend the authority of the Department of Transportation to land shipments and carriers in interstate commerce, the Secretary of Transportation is authorized to formulate regulations for the safe transportation of radioactive materials "which shall be binding upon all carriers engaged in interstate or foreiegn commerce" (18 U.S.C. 834(a)) and which "shall be in accord with the best-known practicable means for securing safety in transit, covering the packing, marking, loading, handling while in transit, and the precautions necessary to determine whether the material when offered is in proper condition to transport." (18 U.S.C. 834(c)). The Transportation of Explosives Act (18 U.S.C. 843 (b)) also contains an express requirement that the Department of Transportation advise and consult with the Nuclear Regulatory Commission before adopting any regulations relating to radioactive materials. (As noted earlier, the responsibilities of the Interstate Commerce Commission under this Act been transferred to the Department of Transportation.)

The authority of the Secretary of Transportation under the Transportation of Explosives Act has been strengthened by the provisions of the Hazardous Materials Transportation Act (49 U.S.C. 1801–1812) which empower the Secretary to promulgate and enforce uniform hazardous materials regulations for all modes of transportation. Pursuant to this authority, the Secretary is authorized to promulgate "regulations for the safe transportation in commerce of hazardous materials . . . [which] shall be applicable to any person who transports, or causes to be transported or shipped, a hazardous material, or who manufactures, . . . repairs, or tests a package or container . . . certified, or sold . . . for use in the transportation . . . of certain hazardous materials." These regulations "may govern any safety aspect of the transportation of hazardous materials which the Secretary deems necessary or appropriate, including . . . [among other things,] packing, . . . handling, labeling, . . . placarding, and routing . . ." (49 U.S.C. 1804(a)). Before issuing any regulations with respect to the routing of hazardous materials, the Secretary of Transportation is required by section 105(b) of the Hazardous Materials Transportation Act (49 U.S.C. 1804(b)) to consult with representatives of the Interstate Commerce Commission. Once those regulations have been adopted, the Interstate Commerce Commission is obligated to implement them to the extent of its lawful authority.

In the exercise of this broad authority, the Department of Transportation has promulgated extensive regulations, codified in 49 CFR Parts 170–189, pertaining to certain types of packaging, labeling and conditions of carriage. These regulations provide controls over the handling, stowage and storage of radioactive materials by carrier personnel and other cargo handlers. The regulations also set forth basic package performance, design and use requirements, and specify standards for marking and labeling radioactive material packages and for the preparation of standardized shipping papers which identify the basic characteristics of the radioactive material packages.

In 1966, in order to develop and implement consistent, comprehensive and effective regulations for the safe transport of radioactive material and to avoid duplication of effort, the Department of Transportation and the former Atomic Energy Commission (now the Nuclear Regulatory Commission) entered into a Memorandum of Understanding.[7] On March 22, 1973, a revised Memorandum of Understanding was signed which is presently in effect. (38 FR 8466, April 2, 1973, copy attached.) Under the provisions of this Memorandum of Understanding, the NRC develops safety standards for packaging design and performance for packages of fissile material and for Type B and large quantities of radioactive material and evaluates designs for containers for these materials. DOT is responsible for developing safety standards for packaging design and performance for all other types of radioactive material packages used in transportation and for evaluating designs for those packages.

DOT is also responsible for developing safety standards governing mechanical conditions of carrier equipment and qualifications of carrier personnel, carrier loading, unloading, handling and storage of radioactive material, and any special transport controls to be provided during carriage, including construction standards for transport vehicles. The Memorandum of Understanding also contains mutual undertakings whereby NRC will adopt regulations requiring NRC licensees not otherwise subject to DOT regulations to comply with the applicable requirements of those regulations when transporting or shipping radioactive material, and DOT will adopt regulations imposing on shippers and carriers subject to its jurisdiction and not otherwise subject to NRC regulations requirements comparable to those contained in NRC regulations. The Memorandum of Understanding also provides that each agency shall conduct an inspection and enforcement program within its jurisdiction, that DOT will be the lead agency in investigating accidents and suspected leakage from radioactive material packages occurring during transit and that NRC will be the lead agency in conducting such investigations when the accidents or suspected leakage occur prior to or after transit.

To date NRC has found the Memorandum of Understading effective in providing an orderly framework in which the regulatory responsibilities of the NRC and the U.S. Department of Transportation can be carried out in an efficient and consistent manner.

IV. NUCLEAR MEDICINE

In the field of nuclear medicine, there are several areas in which the regulatory authority of the Nuclear Regulatory Commission is affected by the statutory responsibilities of other federal agencies.[8] While some of the areas of concern are of long standing, the announcement in 1974 by the Food and Drug Administration of its intention to terminate the exemption for AEC controlled drugs and the subsequent enactment of the Medical Device Amendments of 1976 have made the need to develop consistent regulations and avoid duplicative regulatory controls acute. The Commission is currently engaged in a comprehensive review of its regulatory policies and practices in an effort to determine how these concerns may best be resolved and to clarify NRC's role in the regulation of nuclear medicine.

Under the provisions of the Atomic Energy Act of 1954, as amended, the NRC is empowered to regulate the manufacture, distribution and clinical use of byproduct, source and special nuclear material by means of a licensing program in which the Commission licenses the possession and use of such materials by manufacturers, distributors, pharmacies, researchers, medical institutions and private physicians. The objective of this regulatory scheme is to protect the health and safety of the worker, the patient and the general public in the medical uses of byproduct, source and special nuclear material. In accordance with this authority, NRC now regulates virtually all aspects of the radiation safety of the workers and the general public and certain aspects of the safety and efficacy of radioactive drugs and devices containing these materials with respect to the patients.

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[7] The Memorandum of Understanding was initially entered into between the Interstate Commerce Commission and the Atomic Energy Commission on March 21, 1966. On April 1, 1967, the Department of Transportation assumed the functions and responsibilities of the Interstate Commerce Commission under the Memorandum of Understanding.

[8] The Social Security Administration, for example, controls medical services, including the medical use of radioisotopes, by controlling the reimbursement process for Medicare and Medicaid.

For many years, the former AEC, in consultation with its Advisory Committee on the Medical Uses of Radioisotopes, regulated the safety and efficacy of radioactive drugs and devices with respect to the patient. During this period, the Food and Drug Administration, which is recognized as the lead agency in regulating nuclear medicine, was not empowered to regulate radioactive devices and expressly exempted radioactive drugs controlled by the AEC from its regulatory authority. In 1974, the FDA announced its intention to terminate the exemption for AEC-controlled drugs and the AEC withdrew from regulating the safety efficacy of radioactive drugs. However, the AEC, now NRC, continued to evaluate the safety and efficacy with respect to the patient of certain devices, for example bone mineral analyzers, Pu-238 pacemakers and brachytherapy sources.

The Federal Food, Drug and Cosmetic Act of 1938 (42 U.S.C.A. §§ 301 et seq.) authorized the Food and Drug Administration to regulate the safety of drugs offered for interstate commerce through control of product labeling. Legislative amendments in 1962 gave the FDA tighter controls over drug safety and introduced controls over the efficacy of drugs to foreclose the marketing of safe, adequately labeled drugs that do not work. The Federal Food, Drug and Cosmetic Act of 1938, as amended, also authorized the FDA to control the manufacture of drugs, including radioactive drugs. In 1976, Congress enacted the Medical Device Amendments of 1976, (Public Law 94-295, May 28, 1976, 90 Stat. 539-583) which gave the Food and Drug Administration authority to regulate medical devices similar to its authority to regulate the safety and efficacy of drugs.

In carrying out its statutory responsibilities, FDA employs a system of pre-market approval for drugs and pre-market approval, performance standards or general controls for medical devices. Under this regulatory scheme, FDA requires drug manufacturers to carry out extensive investigational programs to establish the safety and efficacy of new drugs or of new uses of drugs previously approved for other uses before these new drugs or new uses are approved for routine use. During this investigational stage, FDA exercises regulatory control over the use of radioactive drugs and devices.

Although Congress clearly required the FDA to control the availability of drugs for prescribing physicians, it did not intend FDA to regulate or interfere with the practice of medicine. Accordingly, Congress did not give FDA statutory authority to regulate the use of drugs after their approval for routine use. Instead, Congress limited FDA's responsibiilties to determining the safety and effectiveness of durgs and the truthfulness of their labeling. Final judgment as to which, if any, of the available drugs a patient should receive, remained the responsibility of the physician to be exercised by the physician in the light of the information contained on the drug label and other data available to him.

U.S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION,
Washington, D.C., June 17, 1977.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology and Space Subcommittee, Committee on Commerce, Science, and Transportation, U.S. Senate.

DEAR SENATOR STEVENSON: This is in response to your letter of May 19, 1977, to Robert W. Fri, Acting Administrator, U.S. Energy Research and Development Administration (ERDA), concerning Radiation Health and Safety Research.

In accordance with guidance from your staff, we have used your format and matrix to report the following programs under the direction of the Assistant Administrator for Environment and Safety (AES) of ERDA.

Biomedical and Environmental Research (Nuclear Program).

Operational and Enviromental Safety (Part).

Enclosed is an overall summary of the Biomedical and Environmental Nuclear Research program as well as summarizations for each of the following research areas:

Human Health Studies/Health Effects Research in Biological Systems (combined as Health Effects of Nuclear Technologies).

Environmental Studies.

Physical and Technological Studies.

Biomedical Applications (Medical Diagnostic Therapeutic).

Criteria and/or Standards Development.

Surveillance of Facilities and Sites (Monitoring and/or Surveillance).

We have also enclosed responses to each of your questions.

We regret to inform you that our records are not maintained in a manner to supply detailed manpower data but recent experience indicates a cost per scientific man-year of approximately $60,000–$65,000.

If you have any questions concerning this data, please contact my office.

Sincerely,

JAMES L. LIVERMAN,
Assistant Administrator for Environment and Safety.

DIVISION OF BIOMEDICAL AND ENVIRONMENTAL RESEARCH RADIATION EFFECTS RESEARCH

The Division of Biomedical and Environmental Research (BER) has been the primary source for support of research on health and environmental effects of radiation in the Federal government. As a program division under the Assistant Administrator for Environment and Safety (AES), the entire research support of BER was focused on the effects of radiation on man and his environment. The research program included, in addition to applied effects research, (1) support of more fundamental research on the normal structure and function of key biological molecules (e.g., DNA), tissues and organ systems which are sensitive to radiation effects; and (2) support of studies to develop new and improved instrumentation and techniques for the beneficial application of radiation and radioisotopes in medicine, agriculture and biological research.

Although BER has no regulatory responsibilities, the results of this research effort provided a vast amount of data which was used by national and international organizations in recommending standards for human exposure to radiation. In addition, the same data was used to ensure that the development of nuclear energy technologies (both weapons and power reactors) were conducted with maximum safety for individuals in the occupational work forces and the general population.

With the establishment of the Energy Research and Development Administration (ERDA), BER redirected a significant fraction of its research support into the nonnuclear area to be responsive to its new mission in support of all energy technology developments. Since BER is still the primary source of funds in support of radiation effects research in the Federal government,[1] this redirection of research effort, of necessity, required that work in the nuclear research area be critically reviewed, and all projects which were considered to be of lowest priority or near completion were redirected into support of nonnuclear energy technology development. We are continuing to support high priority nuclear energy-related research projects, focusing primarily on the long-term late effects of low dose, low dose-rate exposure of man.

Because of this redirection in research support, the percentage of nuclear-related research supported by BER in fiscal year 1976 decreased significantly from that in fiscal year 1975. In addition, two new categories of research (Multi-Technology and General Science) were created. The Multi-Technology category incorporated research which had been supported to resolve health and environmental problems related to nuclear-energy technology development needs, but were equally applicable to nonnuclear technology development (e.g., research on the effects of thermal effluents on environmental biota, environmental studies (base-line) in off-shore coastal regions of importance in energy-related activities). The General Science category included research that was in support of health and environmental research on the effects of energy-related pollutants on man and environmental biota. This research provides essential information about the complex functional systems (both organismal and ecosystem) that are subject to damage by energy-related pollutants.

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[1] The Nuclear Regulatory Commission supports research in the nuclear area for confirmatory assessment of nuclear-reactor safety which does not overlap BER-supported research.

RESEARCH ON THE POTENTIAL HEALTH EFFECTS OF NUCLEAR TECHNOLOGIES

Part I. Program Justification

A. INTRODUCTION

The Energy Research and Development Administration (ERDA) National Energy Plan emphasizes nuclear energy as one of the most important technologies required to meet energy needs of the Nation in each of the three time frames considered (near-term, 1975–1985; mid-term, 1985–2000; and long-term beyond 2000). During the near-term and mid-term periods emphasis will be placed on overcoming the technological and environmental problems inhibiting expansion of highly utilizable existing nuclear systems—notably light water nuclear reactors. In the long-term period, major emphasis is placed on the successful development of fusion and breeder nuclear reactors.

While the present amount of information on the health effects of radiation and radioactive materials is extensive compared to that available for most other energy effluents, not all problems have been solved or even fully addressed. In addition, challenges have been raised concerning the long-term impact of processes associated with the nuclear fuel cycle on human health. These challenges are particularly concerned with the potential biological effects of very low doses delivered at very low dose rates to large populations and the potential toxicity of plutonium and other alpha-emitting radionuclides.

B. NUCLEAR TECHNOLOGIES

1. Nuclear fission

The ERDA National Plan for Energy Research, Development, and Demonstration (ERDA 76–1) listed three nuclear technologies as being of "Highest Priority Supply." The near-term major energy systems are the light water (converter) reactors, which presently supply about 8% of the total electrical energy production and 2 percent of total energy production in the United States. Nuclear technologies providing nearly "inexhaustable" energy sources for the future are the developing breeder reactors and fusion systems.

There are many aspects of operation common to the breeder and converter (light water) reactor systems. The types of radioactive materials that may be used for fuel and those which are produced depend more upon the particular fuel cycle than on whether a reactor is a breeder (i.e., produces more fuel than it consumes) or is a converter (produces some new fuel, but less than it consumes). There are only two feasible fuel cycles when grouped as to fertile material; these are the uranium and thorium fuel cycles. Both are intially driven by uranium isotopes, but may develop a variety of fertile fissle combinations. The two cycles are summarized as:

Cycle	Fertile nuclide	Fissile nuclide(s)	Sample of reactor type
Uranium	U–^{238}	U–^{235}, Pu–^{239}	Light water reactor, light water reactor with plutonium recycle, and liquid metal fast breader reactor.
Thorium	Th–^{232}	U–^{233}	Light water breeder reactor.

Under certain conditions it is possible to make more fissile material than is consumed with either cycle, in which case the reactor is called a breeder. Combinations of the two cycles are also possible, as is the case for the present High Temperature Gas Reactor (HTGR).

In the uranium cycle, Pu–239 is produced following neutron capture by U–238, and in the process other plutonium isotopes as well as nuclides of americium and curium are generated, together with fission products and activation products of the materials of which the reactor is constructed. In the thorium cycle, U–233 is produced following neutron capture by Th–232. Breeder reactors are designed to extract much more of the total energy from the available fertile material. In the case of uranium this extends by 100-fold the useful energy from uranium already mined or recoverable from proven reserves. In addition, it would be feasible to utilize depleted uranium in the "tailings" from the enrichment plant. Since thorium is a more abundant element than uranium, the energy made available by breeder reactors is even larger. To date the only peaceful nuclear technology that has been introduced on a large scale is the light water reactor. It has also been deemed appropriate, based on current knowledge, to proceed with technological development of demonstration plants of the Liquid Metal Fast Breeder Reactor (LMFBR). A pending decision by the Nuclear Regulatory Commission (NRC) on the use of plutonium as recycle fuel in light water reactors is a major decision as it involves the recovery, handling, fabrication, and the use of plutonium having an isotopic composition very similar to that expected in the LMFBR.

Regardless of the reactor type and fuel used in nuclear fission reactors, the fuel cycle and attendant potential health effects will be similar. The major components of the fuel cycle are mining, fuel fabrication, reactor operation, fuel reprocessing, transportation, and waste handling and storage.

Radiation exposure incident to the development and operation of the technologies can be grouped as internal and external exposures. The external exposures consist of exposure to neutron and gamma radiation. Internal deposition of radionuclides produced and/or handled in the nuclear fuel cycle by man is probably of the greatest concern.

2. *Nuclear fusion*

With respect to nuclear fusion it is premature to identify the health-related research needs in detail. However, current research in support of fission problems will address some of these needs, particularly potential external exposure to gamma rays and internal exposure to tritium. There may be a number of activation products (e.g., niobium) for which we have too little information and which will require further definitive research. These materials will probably include electron capture and positron emitting nuclides which have not been well studied thus far. The biological effects of electromagnetic fields which may be associated with fusion reactors are not well understood at the present time. It is certain that specific research needs will be identified as the technology becomes more advanced and as demonstration plants are put into operation.

C. PLANNING AND ESTABLISHMENT OF PRIORITIES

Plans which allow rapid development of these nuclear technologies must include:

1. Establishment of health research priorities which are coordinated with the development and expansion of the technology.
2. Appraisal and correlation of the national effort in health research in order to efficiently obtain the required information.

Planning to assess the potential health and environmental consequences of developing technologies was initiated in 1973, as part of preparation for Dr. Dixie Lee Ray's report to the President, "The Nation's Energy Future," (WASH–1281). In early 1974 an interagency working group was convened to conduct a similar study of research needs in "Health and Environmental Effects of Energy Use." This planning study resulted in a report prepared for the Council on Environmental Quality (CEQ) and the Office of Management and Budget (OMB) in November 1974, referred to informally as the King-Muir report. These studies involved panels of experts and representatives of science, technology, and government agencies involved in energy-related environmental and health research. The plan and the report incorporate the consensus of research needs and priorities, and describe what the various agencies are funding in energy-related research.

The major research effort on the health effects of ionizing radiation was sponsored by the Atomic Energy Commission (AEC). Advice in identifying areas of needed research was sought and obtained from a variety of sources including the National Academy of Sciences (NAS), the International Commission on Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurements (NCRP). These bodies will continue to be a source of advice for the ERDA.

There has been a gradual shift in research emphasis from concern with the health effects of fallout from atmospheric testing of weapons to the concerns associated with potential health effects of nuclear power production. Many of these concerns have been emphasized in the environmental impact statements for the LMFBR and mixed oxide fuel recycle for light water reactors. Since one of the major challenges of these statements has been based on the concerns for the health and environmental impacts of the transuranic radionuclides, a special working group [the Transuranium Technical Group (TTG)] has been organized. This group, which reports directly to the Assistant Administrator for Environment and Safety, periodically evaluates the current needs for research on the actinide elements. In addition, the Manager of the Biomedical Programs, Division of Biomedical and Environmental Research (BER), has a smaller panel of reviewers which evaluates and recommends research needed on the potential health effects of long-term, low-level irradiation from either external or internal sources.

These efforts have resulted in the establishment of program priorities based on the following criteria: (1) severity of potential health effects, (2) magnitude of the problem (size of population exposed), (3) need for information, and (4) urgency for information.

Part II. Program Overview

Research in the Health Studies category is conducted primarily to define and quantify the impact of energy technologies on human health. To accomplish this goal, it is necessary to (1) identify hazardous energy-related physical and chemical agents, (2) identify adverse human effects induced by these hazardous agents and development and understanding of the pathophysiological basis for such effects, (3) Develop methods for the early detection and diagnosis of energy-related health effects, (4) Obtain quantitative data on dose-effect relationships in humans and several animal species, (5) integrate the quantitative data from the different animals into predictive models that can be used to estimate human health risks under a variety of exposure conditions, and (6) develop improved modes of protection and remediation.

This comprehensive research program on the potential hazards associated with the production of energy from nuclear reactors will provide the data needed to establish and refine guidelines with respect to exposure of persons to ionizing radiation. It will also provide a foundation on which to base cost/risk/benefit analyses relative to health effects.

In regard to existing and developing nuclear technologies, research emphasis centers on evaluating health risks arising from exposures to low levels of external radiation or to radionuclides that may occur in work areas or in the general environment at particular stages of the nuclear energy cycle. Inhalation exposure to radionuclides is considered the most significant potential exposure modality and is receiving major emphasis.

The study of interactive effects occurring when biological systems are exposed to combinations of radionuclides and/or other hazardous agents in addition to radiation is of great importance and will be given high priority. Studies of low doses and dose rates are currently being emphasized because these are the modalities most likely to be encountered in exposure of the general public, and few data are presently available. Late effects including life-shortening, mutations, cancer, and impairment of growth or development will be of primary interest.

Whenever possible, data on potential health risks must be obtained from humans who have been exposed accidentally, occupationally or medically to ionizing radiation. It is essential also to obtain human information on the metabolism and deposition of radionuclides generated and/or utilized in nuclear technologies as the basis for estimating the dose to organs at risk from such materials.

Two of the more important bodies of human data are being developed by the Radiation Effects Research Foundation (RERF) (the former Atomic Bomb Casualty Commission, Japan) (ABCC), and by the Center for Human Radiobiology at Argonne National Laboratory (ANL) (the data for radium in man). The former are more applicable to short exposures of gamma rays and neutrons to the whole body, the latter are more applicable to the prolonged alpha radiation of bone or of epithelial cells that may result from internally deposited uranium, thorium, plutonim, and the other transuranic elements. Because the data available for man are limited, controlled animal experimentation must be used to obtain detailed information about the kinetics and mechanisms of radionuclide metabolism. Animal studies also provide important quantitative and qualitative information about the effects of different exposure conditions and various modifying factors on dose-response relationships. The animal data must be synthesized with available human data to construct predictive models for man. The equation

$$\text{toxicity of Pu in man} = \text{toxicity of Ra in man}\ \frac{\text{toxicity of Pu in dog}}{\text{toxicity of Ra in dog}}$$

is an example of this approach which has guided much of the thinking at the University of Utah project on Pu in dogs. This approach has been amplified and refined in a new theory of bone cancer induction by alpha radiation which has been developed at ANL.

Since no mammal is a sufficient model for man, several species must be used and experimental conditions sought which make possible risk estimates for human populations. By using an interspecies comparative approach, insights are gained into species similarities and differences with respect to sensitivity to hazardous agents, patterns of response, metabolism of internal emitters, and organs at particular risk. The comparison of animal and human data make it possible to determine for any given organ, hazardous agent, or set of exposure conditions which animal species provide the most appropriate model for hazard evaluation in man. Such comparisons are used in developing predictive models applicable to human exposures. Short-lived small animals (rodents) are useful in large-scale experiments designed to obtain statistically valid estimates of risk for low-dose exposures or for studying the influence of exposure conditions or other agents on observed effects. Long-lived large animals are used primarily to study the metabolism of various radionuclides and the pathophysiologic changes associated with diseases which only appear long after exposure.

Full utilization of empirical information will only be accomplished when sufficient understanding of the processes involved in radiation damage exists. It is, therefore, imperative to study changes produced at the organ, cellular, and molecular levels to provide the understanding which will aid in the extrapolation of data from one system to another. Other studies are designed to improve methods for the early detection and diagnosis of abnormalities induced by hazardous agents. These include nuclear medicine techniques which permit lesions to be detected and function to be assessed in single or multiple organ systems. An additional effort of high priority is concerned with developing effective means of protecting exposed individuals against serious injury and with promoting recovery in persons already injured by exposure.

Mechanistic research consists of four different approaches: (1) Studies aimed at understanding the basic nature and normal function of organs and tissues that are uniquely sensitive to ionizing radiation, such as the hematopoietic and immune systems, reproductive cells in the testes, and most epithelial cells that turn over rapidly for normal maintenance of body function; (2) Studies of organ and organ systems that are critical based on the fact that they are the prime target for insult, such as the lung, or because they concentrate hazardous agents or retain them for long periods of time, such as the skeleton, liver, thyroid, and lymph nodes; (3) Studies aimed at developing sensitive indicators of early damage to key organ systems in order to identify effects at earlier times and for ultimate application to man; (4) Studies aimed at the basic understanding of the processes involved in carcinogenic, mutagenic, and teratogenic action of chemical and physical agents.

B. HUMAN HEALTH STUDIES

In order to assess human health risks properly, the magnitude of the dose of a hazardous agent should be quantitatively correlated with the magnitude of the biological effect in man. It is then possible to devise predictive models with which one can calculate estimates of risks or hazards for different levels of human exposure. Predictive models are essential for setting and evaluating human exposure limits, for establishing guidelines with respect to the containment of hazardous agents, and for purposes of making cost/risk/benefit analyses used in long-range energy planning. The development of an adequate predictive capability requires a comprehensive program of research that includes human epidemiological studies, a number of which are currently in progress, to obtain the maximum amount of information on human radiation effects.

Invaluable information on the long-term biological effects of exposure to gamma rays and neutrons in man has come from the ABCC studies on the populations of Hiroshima and Nagasaki. The data collected from this research have provided a major input into all risk estimates for ionizing radiation for

Part III. Detailed Program Description

TABLE 1.—ALLOCATION OF FUNDING OF RESEARCH ON THE HEALTH EFFECTS OF NUCLEAR TECHNOLOGIES

[In thousands]

	Fiscal year—		
	1976	1977	1978
I. Human health studies	10,608	11,348	11,558
II. Studies of radiation effects in experimental systems:			
A. Carcinogenesis:			
1. External radiation studies	5,234	5,067	5,448
2. Alpha	9,152	8,809	9,864
3. Beta-gamma	2,091	1,925	2,032
4. Molecular and cellular	441	414	454
Subtotal	16,918	16,215	17,798
B. Mutagenesis:			
1. External radiation	774	916	721
2. Internal radiation	295	489	570
3. Molecular and cellular	3,414	3,129	3,411
Subtotal	4,483	4,534	4,702
C. Systems damage:			
1. External radiation	1,107	1,687	1,237
2. Internal radiation	1,153	656	715
3. Molecular and cellular	1,518	1,482	1,769
Subtotal	3,778	3,825	3,721
III. Recovery and treatment	674	722	880
Total	36,461	36,644	38,659

TABLE 2.—MAJOR HUMAN STUDIES RELATED TO NUCLEAR TECHNOLOGY

	Fiscal year—		
	1976	1977	1978, projected
Radiation effects to research foundation (Atomic Bomb Casualty Commission)	5,288 or	5,700 or	6,500 or
Marshall Island studies	396	445	480
Center for Human Radiobiology, Argonne National Laboratory (Radium studies)	2,450	2,450	2,650
Transuranium registry	120	130	190
Analysis of radionuclides in human tissues	400	314	290
Health and mortality studies	855	717	779
Epidemiological study of plutonium workers	243	373	460
Total	9,752	10,129	11,349

man that have been made by groups such as the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR) and ICRP. The ABCC was succeeded by the RERF, an organization jointly and equally funded and administered by the United States and Japan. The Science Council, which functions as a scientific advisory committee to the Board of the Directors of the Foundation has recommended certain changes in the scientific program which will be considered by the Board of Directors.

Study of persons who acquired radium as dial painters, chemists, or medical patients provided the early reference data for the setting of maximum permissible levels for radioisotopes, including that for plutonium. Scientists at the Center for Human Radiobiology, ANL, are continuing and extending the study of human radium cases, and have documented 5000 cases of exposure, 1800 of which have been extensively studied to date. Malignant bone tumors (54 observed) and carcinomas of the mastoid and paranasal sinuses (27 observed) are attributable to the radium deposition. All bone tumors were recorded prior to 1970 while 6 cases of mastoid carcinoma have been reported since then. Theoretical studies of the relative biological effectiveness and of the pattern of deposition in bone of Ra–224 (a short-lived radium isotope) were also accomplished recently.

The Center for Human Radiobiology is also doing a followup study of persons potentially exposed to thorium. Mortality data are being obtained on 5000 former employees of a thorium extraction plant, and a morbidity study, by questionnaire, is planned for a sub-group of 500 men with more than one year of work with thorium. A pilot study of detailed examination, including in-vivo radioactivity measurements,' will be done on 100 men randomly selected from the sub-group. Preliminary work has already shown the presence of measurable amounts of radionuclides of the 232Th decay series in some of the workers.

Studies of the inhabitants of the Marshall Islands exposed to fallout after the March 1, 1954, thermonuclear test have continued under the direction of the Brookhaven National Laboratory (BNL). Currently, Rongelap and Utirik Atolls are visited four times each year by a Brookhaven physician who is stationed at Majuro in the Marshall Islands or by one of Brookhaven's medical teams.

Radiological monitoring is conducted on workers engaged in rehabilitation activities and on inhabitants who have returned to the Atoll. This program is providing valuable scientific information regarding late effects of radionuclide deposition in man due to fallout, particularly thyroid effects due to radioiodine.

An epidemiologic program to study past and current plutonium workers at Hanford, Los Alamos, Mound Laboratories, Oak Ridge, Rocky Flats and Savannah River Plants has been initiated. Data will be accumulated on the incidence of disease in life and the cause of death in present and former employees. A comparison is intended between plutonium workers with detectable plutonium deposition, potentially-exposed workers with no record of detectable plutonium deposition, and plant employees who have not been exposed to plutonium. The first cohort will represent the primary study group and the other two cohorts will serve as comparison groups. Suitable populations for study will be developed at each facility, and uniform methods will be applied at the various facilities so that the resulting data can be pooled for analysis. The total population of workers in the study, including controls, will be approximately 12,000.

The detailed examination of a more limited group of plutonium workers exposed during and subsequent to the Manhattan Project at Los Alamos Scientific Laboratory (LASL), will be continued. The original group of 27 workers has been expanded to 250. A more extensive medical, radiological, and health physics examination is provided to these individuals than is possible in the epidemiologic study described above.

The Transuranium Registry operated by the Hanford Environmental Health Foundation (HEHF), collects and analyzes tissues from autopsies on workers potentially exposed to plutonium in ERDA facilities. Valuable data on the distribution of plutonium in various organs of the body have been developed in the study. In most of the autopsies the highest concentrations were found in the tracheobronchial lymph nodes, lung, and liver. The number of identified transuranium workers as defined by the Registry was doubled during the past year. Permission for whole body autopsies was received and the resulting data should provide improved insight into the distribution of plutonium in the skeletal system.

Radioanalysis of plutonium in tissues obtained from autopsies performed on members of the general population is performed at LASL and Pacific Northwest Laboratory (PNL). At LASL, the autopsy tissues have been obtained from several areas in the U.S., while all tissues analyzed at PNL have been obtained from the Richland, Washington area. This program monitors levels of plutonium in tissues of the general population, both near and at a distance from plants where plutonium is handled.

Cytological evaluation of the sputum of uranium miners is being conducted at St. Mary's Hospital at Grand Junction, Colorado. This includes routine screening and followup of suspected cases of lung cancer. An autopsy registry of uranium miners is maintained and an atlas of sputum cytology is being prepared.

The Radiation Emergency Assistance Center/Training Site (REACTS) facility has been completed and is being operated by the Oak Ridge Associated Universities (ORAU). The REACTS followup program has activated a radiation accident registry for the persons who have received excessive exposures in radiation incidents. In support of this activity an experimental program has been initiated in rats on the pathogenesis of gangrene in extremities as a result of the large local doses of radiation that are sometimes encountered in human exposures. Management of the program of controlling and supplying the chelating agent diethylenetriaminepentaacetic acid (DTPA) to plant physicians for use in the treatment of deposited transuranic nuclides has been delegated by the DBER to REACTS. Courses for physicians in the management of radiation accidents are conducted by the REACTS staff and a guest faculty twice each year. Additional courses of this type will be offered in the future for paramedical personnel of nuclear plants.

The ERDA Health and Mortality Study conducted at the University of Pittsburgh in collaboration with groups at the Oak Ridge, Hanford and Mound Laboratories facilities analyzes the mortality patterns of present and past employees of the Hanford plant. The relationship of levels of exposure to longevity is being explored and will be extended to include exposures from internally deposited radionuclides. At Oak Ridge, collection of data from death certificates of deceased workers and from their current employees will have advanced sufficiently to soon permit analysis of the data on the large population of workers (104,000) and their sibling controls (40,000).

A study at the University of North Carolina of tuberculosis patients exposed to radiation during multiple fluoroscopic examinations for the control of collapse therapy is entering the final phase of data collection with the selection and followup of control groups.

Genetics studies in irradiated human populations are important for the assessment of mutagenic hazards associated with the nuclear energy technologies. Several studies of this type are in progress.

Studies of Japanese populations exposed to radiation from atomic bombs have been extensive but have not revealed clear evidence of genetic damage. It is probable that genetic tests used up to now have not been sensitive enough to detect such damage in humans and more sensitive test systems are being developed. For example, a study was recently begun to determine the extent and nature of chromosomal aberrations in the offspring of radiation-exposed individuals. This study, formerly supported by the ABCC appears promising, and will continue under the newly formed RERF. Another promising new system has been developed which utilizes automated equipment to detect several protein variants with great speed and efficiency. Under the new Foundation, preparations for this study by University of Michigan scientists will be accelerated. Another important aspect of this program is the study of mortality among children born to survivors of radiation.

At the University of Denver, a study continues of the chromosomal aberrations in persons exposed to ^{222}Rn or ^{239}Pu. The number and kind of abberations are compared with the length of time and type of exposure to these radionuclides. This work is important to assess the levels of exposure which induce chromosomal aberrations in proliferating blood cells in humans.

Another newly developed test system can detect somatic mutations or errors in the formation of hemoglobin in blood-forming tissues of certain mammals, including humans. Investgators at ANL and Oak Ridge National Laboratory (ORNL) have collaborated to measure these mutations in blood obtained from a group of Marshallese people. This preliminary study has revealed a greater frequency of mutations in the group exposed to fallout and indicates that this hemoglobin system provides a very sensitive method for quantifying somatic mutations.

C. STUDIES OF RADIATION EFFECTS IN EXPERIMENTAL SYSTEMS

1. Experimental animals

a. External radiation studies

Exposure to external radiation is a potential hazard to occupational groups at various stages of the nuclear fuel cycle; large segments of the general population would not be expected to receive significant exposure. Occupational exposures will most likely involve beta or gamma radiation, neutrons, or mixtures of these radiations.

High exposure levels, i.e., 100 rads or more at high dose rates, produce a variety of pathophysiological effects at relatively short time periods following exposure in sensitive organ systems, many of which show remarkable recovery due primarily to cell replacement. Low exposure levels may produce more subtle effects in exposed individuals only after a long latent period (e.g., cancer or other life shortening effects), damage to the developing embryo or fetus, and genetic damage such as recessive mutations observable in the offspring of exposed individuals. Risk estimates for acute effects following high doses of external radiation are well documented and predictions for man are solidly based on many years of research effort.

Present emphasis in research is based on the urgent need for better quantitative information about the health risks (i.e., mutagenesis, carcinogenesis, and teratogenesis) as very low dose-rates near natural background. These are precisely the conditions which could be encountered in large scale nuclear energy development. Since there is no information available for man under these conditions, statistically reliable data of predictive value attainable within the proper time frame will have to come from carefully controlled experiments with both short- and long-lived animals.

Detection of a significant decrease in life-span shortening at a total radiation dose of 4 rads delivered at a low dose-rate would require exposure of about a million mice and would require 25 years to accomplish even in a very large animal facility. Thus a variety of alternative strategies are presently used to provide the required information. A more reasonable approach is to develop predictive and testable models for dose-effect relationships that can be used for eventual extrapolation to man. Also required are bodies of supportive information that will lead to an understanding of the basic molecular and cellular mechanism(s) involved in the production and expression of the effects and that will "build useful bridges" between experimental animals and man.

Several theoretical models have been advanced which approach a capability of predicting life-shortening or carcinogenic risk at low radiation doses. All of the most advanced theories are based on analysis of information already available, all preclude the need for the multimillion animal sample sizes and all emphasize dose-rate as a more important experimental parameter than total dose for risk estimates from low linear energy transfer radiation. These models are experimentally testable and are being tested at ORNL, ANL, and New York University. At ANL a multispecies analysis will provide the proper scaling factor to be used for short- and long-lived animal species. At ORNL and ANL the influence of radiation quality is being evaluated by comparing the relative biological effectiveness for fission neutrons relative to gamma rays.

The importance of dose-rate can be exemplified by the following findings: (1) Studies utilizing beagle dogs have shown that some diseases that shorten life span are dramatically dose-rate dependent—septicemia and anemia occur at high dose-rates while leukemia occurs at low dose-rates (~5 rads/day). Since all these diseases are due to radiation-induced perturbations in bone marrow differentiation, the differential dependence on dose-rate is remarkable and worthy of increased effort to establish the mechanisms in terms of damage to the hematopoietic system. These studies are now being extended to the study of lower dose rates. The effect of chromic exposure on the developing fetus is also under study; (2) At ORNL it has been found that some types of cancer, notably lung cancer in mice, show a maximum incidence in the range of 5 rads per day. Thus, at least for some types of neoplasia, there appears to be an optimal dose rate at which the highest incidence of tumors will be observed.

All radiation standard setting groups and most risk estimates for man have assumed a linear dose response based only on total radiation dose. The results from the large scale experimental animal studies involving exposures to low linear energy transfer radiations (X- and gamma-rays) are demonstrating that this consistently overestimates the risks for the somatic effects from this type of exposure. While it is still not clear if the dose-response curve for this type of radiation is linear at low dose-rates, it is increasingly apparent that low dose-rates are less effective than high dose-rates in the induction of cancer. Thus the current radiation exposure guidelines for exposure to X- and gamma-rays and beta particles most probably are conservative. It is anticipated that future groups may revise the risk estimates based on the large amount of information developed from the studies in experimental animals.

b. Studies with internally deposited radionuclides

The primary purpose of animal studies with internally deposited radionuclides is to develop a qualitative and quantitative biological basis for assessing the risk to man associated with the exposure to radioactive materials. The research program consists of studies of the metabolism and toxic effects of radionuclides in experimental animals which can be compared with the results of epidemiological and metabolic studies on man. The animal work consists of carefully controlled laboratory experiments in which the metabolism, dosimetry and toxic effects are investigated in a variety of mammalian species with a view to understanding the comparative toxicity and metabolism in sufficient detail to reliably extrapolate to man, using appropriate mathematical modeling suitably tested in experimental animals and man.

The metabolic, dosimetric, and toxic effects studies in animals take into account various routes of exposure (i.e., inhalation, ingestion, intravenous, or intramuscular injection), different physicochemical forms of nuclides, age of the animals, specific metabolic traits of the animals, and the particular suitability of selected animals as models for physiological and pathological processes in humans. The purpose of metabolic studies is to identify the factors influencing localization of radioactive materials in organs, tissues, and cells. The purpose of the dosimetric and toxic effects studies is to understand the types, mechanisms, and degrees of damage in order to assess the biological hazards resulting from incorporation of radionuclides. Collectively, the research program is designed to assess the severity and the nature of the radiobiological lesions from internally deposited radionuclides leading to possible physiological, biochemical, or cytological changes.

To obtain statistically valid data on late somatic effects, life time observations on large groups of animals exposed to graded doses of radionuclides are required. These studies have utilized several species with a range of life spans (primarily rodents and dogs). Since the rodent and the dog are known to exhibit important differences with respect to metabolic patterns and organ function, metabolic studies are in progress on a smaller scale in two other long-lived species, miniature swine and subhuman primates. This comparative multispecies animal approach allows data to be extrapolated to man with greater confidence than would otherwise be possible.

Another major concern, from an occupational and public health standpoint, is the assessment of risks that result from internal exposures to low levels of radiation. The health effects program of ERDA is concerned with accumulating quantitative data on late somatic effects, particularly life shortening and cancer incidence. Since inhalation is expected to be the most common mode of internal deposition of radionuclides in man from nuclear energy operations, exposure of animals via the inhalation route is emphasized. However, in general populations, uptake via the gastrointestinal tract may also be important and work continues with this exposure modality. The response after injection of radionuclides is also studied, since this provides the opportunity to deliver selected doses in well-characterized forms, and to study the comparative metabolism and effects of various radionuclides in several species.

Since it is not possible to conduct comprehensive studies of all radionuclides of interest under a wide variety of conditions, they are studied on a priority basis which depends primarily on the needs established by developing technologies. Those under intensive study now include uranium and the important transuranium elements, principally isotopes of plutonium, americium, and curium; selected fission products, particularly isotopes of strontium, yttrium, cerium, ruthenium, iodine, krypton, and tritium; radium isotopes; and radioisotopes associated with uranium mining, radon, and its radioactive decay products. Studies on the metabolism and effects of high-specific activity uranium isotopes such as in the HTGR and the Light Water Breeder Reactor (LWBR). Studies of inhaled internal emitters are conducted primarily at PNL and at the Inhalation Toxicology Research Institute (ITRI); injected internal emitters are studied at LASL, University of Utah, University of California at Davis, University of California at Berkeley, ANL, PNL, and New York University; ingested internal emitters are studied at PNL, the Comparative Animal Research Laboratory (CARL), and University of California at Davis; incorporation from puncture wounds has been studied at Colorado State University.

The results of animal research (1) provide information required in support of development decisions for various nuclear energy options (both fusion and fission), (2) provide scientific information needed in the process of technology development, review of standards and regulatory aspects, and (3) contribute towards a better scientific and public understanding of health risks associated with the use of nuclear energy.

The information developed from the spectrum of studies on the effects of internally deposited radionuclides in man and experimental animals has been used to establish reasonable exposure guidelines for man. The emphasis of the current research is to provide information for the refinement of these guidelines either upward or downward and to provide positive answers to the significant questions that have been raised relative to the unique dosimetric and toxicity problems from internally deposited radionuclides (e.g., the "hot particle" question).

(1) *Metabolism and effects of alpha-emitting radionuclides*

Knowledge of the health effects resulting from exposure to plutonium is of great importance because of the production of plutonium in current nuclear reactors and because of its projected use as a major nuclear fuel in the fast-breeder reactor. The toxicity of plutonium is markedly influenced by its physicochemical form and route of entry into the body. Previous studies conducted at ANL, PNL, and the University of Utah demonstrated that exposure of rodents and dogs to relatively high doses of plutonium by inhalation or injection results in an increased incidence of tumors in the lung, liver, and bone with the target organ being dependent on the route of exposure and the eventual distribution within the body. The major effort in determining the risk of exposure to plutonium is directed toward an understanding of the factors and events which lead to this tumor formation and toward the identification and quantitation of other effects at doses down to the equivalent of presently accepted limits for occupationally exposed humans. The influence of age and metabolic disturbances on plutonium metabolism and carcinogenicity are also under study at the University of Utah, PNL, and ITRI.

Alpha-emitting aerosols may be classified broadly as being soluble and insoluble. Upon inhalation, insoluble aerosols remain in lung tissue for long periods of time, irradiating cells in the vicinity of the particles. The resulting radiation exposure is very nonuniform and highly variable depending on the number of particles, the size and activity of the particles, and the degree of translocation both on a micro and macro scale within the lung.

There are three major complementary programs designed to assess the degree of risk associated with particles of plutonium dioxide (these are sometimes referred to as "hot particles" if they contain sufficient radioactivity). At ITRI a major series of inhalation exposures of rodents and beagle dogs is underway with uniformly sized (monodisperse) alpha emitting particles. The experimental design includes variability in particle number, size, and specific activity. Although monodisperse aerosols are difficult to generate and rarely occur naturally, these studies should determine the relative risk of pulmonary neoplasia associated with nonuniform vs. uniform distribution of radiation dose to the lung tissue.

A second experiment relating to the hot particle question is being conducted at LASL, in which particles containing plutonim of varying specific activity are deposited in the pulmonary capillaries of Syrian hamsters following injection into the jugular vein. While these exposures differ from inhalation in that translocation to lymph nodes does not occur and the particles remain relatively fixed in location, they do permit precise quantitation of macro- and micro-dosimetry. The carcinogenic response after administration of varying numbers of particles of different sizes and specific activities can then be correlated with differences in dose distribution.

However, since aerosols encountered in nature are varied and polydisperse (i.e., composed of a variety of particle sizes and shapes) it is obligatory to determine the biological effects of such inhaled aerosls. These studies are underway primarily at PNL. Past studies have shown that lung tumors are produced by relatively high lung burdens of inhaled Pu-239 oxide. Similar studies with inhaled Pu-238 indicate that the skeleton may be the tissue at greatest risk for this plutonium isotope as osteosarcomas are produced at a higher incidence than are lung tumors. This difference in critical organ is thought to reflect the greater solubility of the ^{238}Pu. These studies are being extended to lower initial lung burdens which approximate the equivalent of the occupational exposure limits for inhaled plutonium. These studies at ITRI, LASL and PNL are expected to provide information concerning the relative importance of particle size, particle activity, radiation dose and identification of the cells at risk in the induction of lung cancer from inhaled alpha-emitting particlates.

Plutonium nitrate is another major form of plutonium handled by workers involved in nuclear fuel reprocessing. Animals exposed to aerosols of more soluble forms of actinides have shown both lung cancer and osteosarcoma. It is, therefore, uncertain whether lung or bone cancer is the more likely expression of damage in man and what the magnitude of risk may be from low level exposures. Accordingly, low level inhalation exposures of beagle dogs to plutonium nitrate are in progress at PNL and in rodents at PNL and ITRI.

Range-finding studies of the effects in rodents of inhaled oxides and nitrates of plutonium, curium, and americium are in progress at ITRI and PNL. Results from these studies will be used to determine the desirability and necessity for designing detailed studies in large animals (dogs, miniature swine, or primates).

In addition to the prevalence of these radionuclides in the nuclear fuel cycle, the importance of these studies is related directly to a variety of beneficial purposes for which these radioisotopes are used, such as thermoelectric sources (e.g., Pu-238, Cm-244 in heart pacemakers and navigational equipment) and irionization sources (e.g., Am-241 in smoke detectors).

Although chronic or repeated inhalation exposures are considered as possible modes of radionuclide exposure, few data exist concerning the relative hazard of this type of exposure. Therefore, studies on rodents and dogs subjected to repeated exposures to radioactive aerosols were recently initiated at ITRI. Preliminary studies with fission product radionuclides suggest a greater retention of the aerosols in the lung following repeated inhalation exposures than after a single exposure.

The isotopic composition (specific activity) and particle matrix of plutonium produced in nuclear power plants is considerably different from that of "pure" Pu-238, important for space/nuclear power sources, and from that of P-239, important for weapons, which have been used in past studies. Plutonium nuclear reactor fuel may be intimately incorporated with uranium, which will comprise most of the particle mass. In addition, the associated of plutonium containing aerosols with other elements, particularly sodium, might be expected in the LMFBR in the event of an accident, thereby presenting the possibility of a combined risk of inhalation of plutonium and sodium aerosols. Studies at PNL and ITRI are investigating mixed oxides of uranium plutonium, curium, and americium, while mixed sodium—plutonium aerosols are being studied at PNL.

Research on the occupational hazards of aerosols associated with uranium mining continues at PNL, where the toxicity of inhaled radon and its daughter products is being evaluated by inhalation experiments with dogs and rodents. An important feature of this work is that information is being gained on the mechanisms by which exposure to other components of mine air (ore dust, diesel fuel exhaust) and cigarette smoking affect the pulmonary response to inhaled radon daughters.

Although much work on the radiological and toxicological properties of uranium was conducted during and shortly following World War II, little work has been conducted on the higher specific activity isotopes of uranium such as U–233 and U–232 which are used and formed in thorium cycle reactors, such as the HTGR. Accordingly, studies of the disposition and chronic effects of inhaled U–232 and U–233 will be initiates.

The major studies of the effects of alpha-emitting radionuclides deposited in the skeleton are being conducted at the University of Utah. Comparative tumorigenic effects of plutonium, americium, curium, thorium, californium, and radium are being studied after intravenous injection, primarily in the beagle dog. Since there are considerable human data on the induction of bone tumors (osteosarcoma) in radium dial painters, the results of these studies will permit the direct comparison of the effects of radium in the beagle dog at Utah and University of California, Davis, with those observed in humans. The effects of other injected alpha-emitting radionuclides (primarily plutonium and other transuranium elements) in the dog are being compared with those from radium, to provide a basis for the extrapolation of toxicity data from dog to man. Other parameters including the species characteristics, bone dynamics as a function of age, the local bone dosimetry, cells at risk, and the histopathology of induced lesions are being investigated to further strengthen the basis for extrapolation. Studies of the behavior of internal emitters in soft tissues, particularly the liver, are also important, and studies are needed to define translocation rates between tissues. Mathematical models are being refined which relate radiation dose and dose-rate to cancer induction. Studies are now in progress to study the response at doses corresponding to levels equivalent to occupational body burden exposure limits for plutonium in man.

Although the mammalian gut discriminates strongly against most plutonium and transplutonium compounds, there is some absorption, depending upon the chemical form. Previous studies have shown that following gastrointestinal absorption, the skeleton will accumulate the highest radiation dose; accordingly, injection studies are directly relevant to internal distributions in that the ingested material enter the bloodstream. Alphaemiting radionuclides are also incorporated into skeletal tissue following inhalation when they are translocated from the tracheobronchial lymph nodes and lung. The aborption and translocation kinetics of ingested isotopes of plutonium, uranium, neptunium, curium, and californium are being determined in studies at PNL and CARL in order to more accurately predict the amount reaching critical tissues under a variety of physiological and environmental conditions.

The ultimate biologic fate of radionuclides and the effects produced by them are dependent on a number of factors including age, pregnancy, dietary status and drug intake. Studies being performed at CARL and PNL are examining the cross-placental and milk transfer of several radionuclides as well as the influence of age, diet, and other factors on the metabolism and long-term effects of these radionuclides.

At Lawrence Berkeley Laboratory (LBL), the kinetics and distribution of ^{238}Pu, ^{241}Am, and ^{90}Sr at the organ and cellular level are under study in two subhuman primate species, rhesus and cynomologous monkeys. At New York University metabolic studies of ^{241}Am, ^{244}Cm, and ^{210}Pb are underway in another subhuman primate, the baboon, and the kinetics and distribution of these radionuclides are being investigated.

(2) *Metabolism and Effects of Beta-Gamma Emitting Radionuclides*

While alpha-emitting radionuclides are a major area of concern because of their relatively high toxicity compared to beta-gamma-emitting radionuclides, it is essential to recognize that large quantities of beta-gamma-emitting fission product radionuclides are produced in nuclear fission. These radionuclides are separated from plutonium or uranium during fuel reprocessing and then stored as wastes. In addition, certain of these radionuclides such as tritium, krypton, and carbon may be released to the environment under normal operating conditions of the fission fuel cycle. Therefore, the potential health effects of the fission product (beta-gamma) radionuclides must be evaluated.

The comparative metabolism of a variety of fission products in mice, rats, dogs, monkeys, and man is continuing at LASL, including work on alkaline metals such as Cs–137 which is an important radionuclide in fallout and a waste product of all reactor fuel cycles. Studies in a variety of animals of the magnitude and mechanisms of gastrointestinal uptake of Ce–144 are in progress at the CARL to better understand the potential hazard from the ingestion of fission products. At Cornell University studies of the uptake of important fission products in the plant-cow-milk food chain are continuing. However, in the latter studies increasing attention will be devoted to actinides in future years.

A comprehensive program is continuing at ITRI concerning the behavior and biological effects of a number of inhaled beta-gamma radionuclides (primarily fission products), including soluble and insoluble forms of ^{91}Y, ^{90}Y, ^{137}Cs, ^{90}Sr, ^{144}Ce, and ^{106}Ru. Exposure conditions have been used which deliver a wide range of dose rates and total radiation doses to the lung. The emphasis in these studies is to establish the relationships between radiation dose patterns and the resulting biological effects. Results from these studies will be used to compare the effects of low linear energy transfer radiation with those produced by high linear energy transfer radiation from the inhaled alpha emitters being studied at PNL and ITRI.

Current permissible environmental levels for the fission product gas krypton-85 are based on calculations rather than on known biological effects. In order to obtain biological information on the toxicity of inhaled krypton, experimental animal studies with inhaled Kr-85 have been initiated at PNL. In addition, a program at BNL is investigating the metabolism of this radionuclide when very low levels are inhaled by man.

Extensive studies are in progress at the University of California at Davis on the effects of chronically ingested and injected strontium-90 and radium-226 in dogs. These studies are providing an index of estimated risk to humans by correlating the incidence of osteosarcoma and other diseases in the beagle with the same diseases which appeared in radium dial painters. These studies have shown a dose-response to Sr-90 that is apparently non-linear, and they may show a significant dose-rate effect. These and related studies at PNL in which miniature swine (another long-lived species) ingested ^{90}Sr daily will provide a sound basis for the setting of human exposure limits for internally deposited ^{90}Sr. Studies are in progress at PNL in rats, dogs and miniature swine to evaluate the acute lethal hazard for ingested ^{106}Ru in connection with reactor or spent-fuel reprocessing accidents.

Tritium, a heavy radioactive isotope of hydrogen, is produced in fission processes by some neutron interactions with light elements and in fusion of deuterium process by neutron irradiation of lithium. It is expected to be produced in abundance by reactor cycles employing heavy water, and is produced to a lesser extent in other uranium and thorium fuel cycles. At Lawrence Livermore Laboratory (LLL) the effects of tritiated water and external radiation in the mouse and monkey female germ cells and developing fetus are under study. The production of dominant lethal mutations in mice by tritium at exposures equal to 1 to 100 times the present concentration limits in water is under investigation at BNL.

Krypton-85 is another nuclide produced by light water reactors. Studies of its toxicity in rodents are being performed at the Health Effects Research Laboratory of the Environmental Protection Agency (EPA) under an interagency agreement between the ERDA and the EPA.

Studies of radioiodine (^{131}I) effects were originally carried out because of its presence in fallout, but it is an important radionuclide in routine and accidental releases in the nuclear fuel cycle. In addition, ^{129}I is a long-lived fission product potentially released during fuel reprocessing in all fission fuel cycles. Several experimental programs address these problems. At the University of California at Davis, the effects of lifetime exposure to ^{129}I are being investigated in the rat. At the University of Tennessee, a global thyroid collection network is maintained which is useful for studying changes in radioiodine levels with time and the radium contents of thyroids; these studies provide an important bank of tissue for ongoing studies. Other work at the University of Tennessee includes studies of effects of iodine deficiency on reproduction and development in rats and of prevention of accumulation accelerated excretion of iodine from the thyroid. At Case Western Reserve University, physiological and morphological changes in thyroid tissue resulting from ^{131}I administration are studied in rats. When human thyroid tissue becomes available from patients treated with ^{131}I for hypothyroidism, collateral studies of morphology are made. Studies at PNL are comparing the long-term effects, including carcinogenesis of ^{131}I administered to immature rats. At the Cornell Medical Center, studies have shown that administration of stable iodine to iodine-deficient dogs produces cell killing. Expanded studies are contemplated to relate this research to potential lesions in man; if a similar lesion develops in man, this effect may have to be considered in the use of stable iodine to prevent radioiodine accumulation in the event of reactor accidents.

2. Studies of radiation damage in organ, cellular, and molecular systems

Studies of the pathogenesis and biological mechanisms of radiation damage are also essential to the development of radiation protection standards and the development of techniques to alleviate the biological effects. The toxicity studies described in previous sections are providing information on the response to radiation in the intact animal. In order to understand these observed effects and extend the application of knowledge gained from animal experiments, it is essential to understand the basic mechanisms that are responsible for these biological effects.

This type of research is conducted in university-based laboratories and in the following ERDA laboratories: ORNL, BNL, ANL, PNL, ITRI, LLL, LASL, Michigan State University Plant Research Laboratory, and the University of California, Los Angeles.

a. Critical Organ Systems and Pathophysiology

The hematopoietic system is easily perturbed by ionizing radiation and leads to disturbances of production of both white and red blood cells. These disturbances lead to a variety of diseases including septicemia, anemia and leukemia. Studies at LBL, BNL, and ORNL, as well as at a number of university laboratories involve an assessment of the normal function of this system.

The immune system comprises the first line of defense of the body against infectious and malignant diseases and is sensitive to a number of chemical and physical agents. Studies at Franklin McLean Memorial Research Institute (FMMRI) and a number of universities attempt to understand how and when the immune system functions and is perturbed. The role of immunosuppression and/or possible viral activation in the development of radiation-induced tumors is under investigation at PNL, ANL, University of California at Davis and the ITRI. These studies are utilizing animal models of radiation-induced tumors developed from the results of the long-term toxicity studies.

Both the reproductive system and the developing embryo are sensitive to radiation which can induce sterility or a variety of disease states in the offspring. At LLL and two universities, studies of normal development are conducted. Studies at PNL are examining the embryocidal and teratogenic effects of prenatally-administered plutonium, americium and curium.

Pulmonary injury and neoplasia development are well-documented effects of inhaled radionuclides. Studies are in progress at PNL, and ITRI to determine the underlying mechanism of the damage. These include studies on the biochemistry of collagen synthesis in the development of pulmonary fibrosis and studies on the synthesis of pulmonary surfactant in injured and normal lung. The inflammatory response of the lung following radiation injury is being investigated and compared to the response of the lung to other types of injury. The role and function of the pulmonary macrophage in pulmonary clearance and in the pathogenesis of pulmonary disease is also under investigation. In order to understand more about the development of pulmonary neoplasia and the cells at risk from inhaled radionuclides, it is essential that more be known about the kinetics of the pulmonary cells. Studies on the turnover times of lung cells are being initiated.

The skeleton is a site for the eventual deposition of many radionuclides. Studies have shown that the critical cells for the development of bone-related tumors are located on bone surfaces. Thus, the bone surface to volume ratios and the rates of bone remodeling are critical factors for interspecies comparisons.

b. Developing of Improved Bioassay Screening Systems and Early Indicators of Damage

A battery of cytological, biochemical, and physiological indicators of cellular, tissue, and organ damage are under development in the ERDA laboratories. Several of these systems will ultimately provide improved means of detecting and monitoring damage to the human population from exposure to radiation as well as from other agents. At the same time, such tests can provide a realistic method for extrapolating results obtained in experimental animals to normal and susceptible segments of the human population. Promising methods are incorporated into both animal and human research efforts as expeditiously as possible.

New technologies in nuclear medicine research are being exploited to develop the use of radionuclides and new radiopharmaceuticals for the early diagnosis of human diseases. This objective is pursued by supporting research at ERDA laboratories and several university medical laboratories. In addition, the ERDA laboratories conduct cooperative programs both with investigators in the basic sciences and in clinical medical practice.

The nuclear medicine research program develops radionuclide procedures which provide unique diagnostic information for the assessment of organ structure and function. Enhanced organ imaging techniques occupy a major interest in the program. Due to recent advances in instrumentation, there is a growing emphasis on assessment of organ function in general and pulmonary and cardiovascular functions in particular.

A comparative study at FMMRI demonstrated the superiority of nitrogen-13 ammonia over technetium-99m-labeled phosphates to define myocardial infarcts. Research on labeling metabolic compounds with the cyclotron-produced short-lived isotopes is being actively pursued. Use of such compounds will provide data heretofore difficult if not impossible to acquire.

A cooperative study initiated by ORNL with six medical institutions using a common clinical protocol to evaluate potassium-43 in detection of coronary artery disease has just been completed in which over 250 patients were studied. Although the final analysis of the data has not yet been completed, the following preliminary conclusions may be drawn. Changes in the K–43 images were observed in patients where conventional tests failed to detect abnormalities. Also, use of K–43 appeared useful in identifying certain categories of high risk patients that should be excluded from surgical intervention (e.g., by-pass operation). In general, K–43 may be more sensitive than other techniques for detection of single artery disease prior to onset of myocardial damage.

Development of new mehods for measuring lung function are being continued at BNL. An important advance in this area was made by the development of a new class of agents (radioactively-labeled simple amines). These agents localize in the lung and subsequently are metabolized by lung tissue. Administration of these agents not only allows imaging of the lung but provides valuable information on the metabolic integrity of the tissue itself by measuring the rate of release of "$^{14}CO_2$" in the expired air. Combined with more conventional ventilation and perfusion studies, use of these agents will open up new avenues to study lung disease

Comparative assessment of a lung function in a small randomly selected population utilizing dry aerosol techniques, radioactive xenon, and conventional techniques are being conducted at the University of California, Los Angeles. In addition, preclinical studies in heart physiology are being expanded in order to expedite the clinical application of a tomographic scanner for positron emitters. An active program in developing new chemical labeling techniques using short-lived isotopes of various biologically active compounds is also being carried out. One of the products of this program (alcohol labeled with radioactive fluorine) is being assessed as an agent to measure regional brain perfusion.

c. Molecular and cellular studies

The initial action of radiation on cells includes the primary electronic events following initial absorption of radiation energy, the transfer of energy within and between molecules, and the formation of chemical products. Chemical changes in the cellular nucleic acids appear to be the most important, although changes in cell membranes can also be detrimental. Alterations in nucleic acids which comprise the information storage and transfer system can cause permanent genetic damage if not repaired. Interference with the normal information processing system can cause a variety of cellular effects ranging from temporary delays in normal cell growth and division to the formation of aberrant cells to cell death. All aspects are being studied in order to provide the basis for extrapolating these events in mammalian cells to human populations. In addition this work is useful for improving the designs of radioprotective drugs and for synthesizing new chelating agents to remove incorporated radionuclides.

Studies on radiation's initial primary electronic events are being conducted on nucleic acids, proteins, peptides, and other important biomolecules. The development of new and sophisticated instruments are leading to the determination of the actual primary events by permitting measurements of reactions to be made in nanoseconds and by means of low temperature studies. Transfer of energy within and between molecules is being studied to establish the location of energy sinks in biomolecules. An important problem under investigation is the transfer of energy along the polynucleotide chain of DNA to specific bases which may then become centers of high chemical activity. The role of oxygen, free radicals, and reducing compounds as participants in energy transfer processes and modifiers of chemical reactivity are being vigorously pursued. The information gained through these studies provides opportunities for interfering with energy transfer processes in order to prevent cellular damage and to channel the energy into therapeutically useful directions. Also, knowledge about the final chemical products can provide a means for assaying exposure and for establishing the substrates on which repair enzymes must act.

Alterations in cell membranes brought about by radiation are being pursued through studies of radicals generated in biomolecules outside of the cell interacting with the cell membrane. Pulse radiolysis and flash photolysis are being used to study the surface structure of ions and their movement through membranes.

It is now well known that the radiosensitivity of cells varies throughout the cell cycle; most of the projects described below the studies are conducted with respect to the different phases of the cell cycle. These studies include: the action of high and low linear energy transfer radiation; the metabolism of irradiated cells to explore the metabolic derangements that lead to death; and the organization and integrity of the information repository and transfer system.

Studies are underway at ANL, LASL, and the University of Utah to develop an understanding of the chemical binding and subcellular localization of plutonium and other transuranium radionuclides. A better understanding of the kinetics of transport and cellular binding will provide a more rational approach to such factors as interspecies differences in the metabolism of these elements and their eventual removal from the body. It has been shown that the plutonium in the blood is transported by the iron-binding protein, transferring, and studies are being initiated to determine how their protein releases plutonium into the liver and skeleton.

The exposure of cells to ionizing radiation or the intracellular presence of decaying radioisotopes produces DNA damage that may have lethal or mutagenic consequences. Such energy emissions are especially suspect as the cause of single-strand and double-strand breaks in DNA. Radiation-induced free radicals that are labile but hyper-reactive chemically are also generated and contribute to chemical mutagenesis. Ionizing radiation is known to produce damage to pyrimidine- and purine-base components of DNA. Increasing evidence is emerging to suggest that the various types of radiation damage are reversible by enzymatic repair mechanisms. Thus far, repair mechanisms can be classified within three groups: (1) those which specifically reverse a particular chemical change in DNA, (2) those which remove the damaged sequence, or (3) those in which the damaged DNA strand is entirely replaced in the process of DNA replication. Recent results have indicated some degree of DNA repair from high linear energy transfer radiation.

Mechanisms that correct molecular damage to DNA utilize enzymes whose formation is controlled by chromosomal genes. Deficient mutations in genes that code for repair enzymes create increased susceptibility to the particular variety of DNA damage that is ordinarily corrected by that repair system. Such vulnerability may culminate in early onset of cancer, aging, and other disease syndromes in man. The characterization of radiation-sensitive mutants is a powerful genetic approach that is currently being exploited in a wide spectrum of experimental systems. Increased susceptibility of various mutants to irradiation implicates the roles of the deficient genes in the repair process, especially after confirmation in vitro of a particular enzyme defect.

The enzymes that are involved in DNA repair catalyze reactions which are also involved in such processes as DNA replication or DNA recombination. In fact, there is evidence that some of these enzymes may have multiple, overlapping functions. Therefore, alterations in repair enzymes as the result of mutations may simultaneously alter other cellular functions. Considerable emphasis is being given to the sorting out of a large number of complex gene-enzyme relationships, taking into account the heterogeneous array of different repair systems as well as the possible multi-functional roles of repair systems in other DNA processes. Such gene-enzyme relationships can now be studied in human cells cultured in vitro, and this approach is being emphasized at ORNL and BNL. The understanding of the particular action of each DNA-damaging agent and its cognate repair mechanism is necessary in order to assess the possible synergistic effects of combined exposure to mutagenic agents.

3. Genetic studies

The program in radiation genetics is designed to define the level of genetic damage that would result from subjecting human populations to radiation exposure. Somatic mutations and their significance are also being assessed. Damage to the genetic material can be detected and measured as specific endpoints such as an increased rate of mutation of individual genes, or of induction of various kinds of chromosomal aberrations, etc. These are the endpoints that are detectable and measurable in the laboratory and are usually studies in experimental organisms, although on occasion valuable observations can also be made on human populations that have been exposed to radiation.

Because of the limited availability of exposed human populations, the limitations on the procedures that are possible and permissible with human subjects, and the limited number of humans exposed to significant doses of radiation available for investigation, the studies on irradiated humans are primarily confirmatory in nature, and by themselves cannot supply an adequate basis for making risk estimates for the genetic effects of radiation. Even when human studies can be made, experiments with animals, and with cellular and molecular systems must supply the understanding of genetics events needed for interpretation, as well as much of the methodology.

The information that is needed in making estimates of human damage must come from studies in a variety of organisms, each chosen for its suitability in the answering of specific questions related to mutagenesis and its consequence. The questions that must be answered are: (1) What is the sensitivity of the human germ plasm and how can we estimate the rate of radiation-induced mutations? For example, what kind of numerical relationship would hold between mutation in mice and in humans? (2) Given an accurate estimate of the amount of damage to the human germ plasm, what does it mean in terms of an added burden of genetic disease and disability? Studies must be directed at mutation processes and the nature of the mutation condition as well as at population processes, at mechanisms in the production of aberrant individuals, and the mechanism by which defective genes are eliminated from the population.

The major kinds of genetic damage are effects on single genes ("point mutation"), and effects on chromosomes (chromosome aberrations), the latter being of two kinds, rearrangements of chromosomes that may affect the transmission of complete sets of genes to offspring, and numerical aberrations, where the chromosomes may be structurally intact, but the wrong numbers of chromosomes are transmitted. Each of these can contribute to serious development defects.

a. Studies with external radiation

Currently, genetic risks estimates of radiation-induced increases in point mutations are based on three kinds of considerations: (1) the rate of induced mutation relative to the spontaneous rate, (2) the incidence of human genetic disease, and its dependence on recurrent mutation, and (3) estimates of how changes in mutation rate will, through changing gene frequencies in the population, alter the incidence of various kinds of human disease. Evaluation of (1) and (3) currently cannot be made with data available from humans, and recent surveys of human populations have given radically different pictures of item (2), and the incidence of human genetic disease.

(*1*) *Measurement and estimation of gene mutation rates*

The raw data on induced mutation rates that are currently most used for the genetic risk of radiation to man are those derived from mouse studies that were conducted for more than two decades at ORNL. These studies have played a key role in evaluating the genetic hazards of radiation for humans and have been used in setting the standards for radiation exposure. These studies have shown a marked difference in sensitivities of germ cells of the two sexes, and have shown further that there is a markedly lower rate of damage when the exposure is protracted that when given in a short time interval.

Studies on human radiation-induced genetic mutations have in the past been limited to studies on early mortality of the offspring of the Japanese survivors of radiation released by atomic bombs. These studies are now being expanded to include investigation of rare protein variants in hemoglobin in the Japanese survivors. It is not yet certain that these studies will permit precise estimation of the human radiation-induced mutation rate, or even what fraction of the total mutational spectrum will be represented in these studies. They will be useful, however, in making comparisons with other organisms and should permit greater confidence in making human risk estimates.

Since it is necessary to base refinements in genetic risks estimates to man on information from sources other than human germ cells, it is essential to recognize the limitations of the methods used. Cells in different stages of development may differ greatly in radiosensitivity, and marked differences between species are also found. In order to extrapolate from the effects observed in lower organisms to the potential effects in man, it is necessary to develop methods of making meaningful comparisons. Empirical comparisons, using a wide variety of organisms should define a range of sensitivities that should include human radiation sensitivity. However, confidence will be improved as we learn more about the nature of the molecular events involved in radiation damage and its repair.

Mutation studies in viruses and in bacteria (prokaryotes) have given invaluable insight into the nature of mutation, the nature of gene action and its control. However, genes in higher organisms (eukaryotes) have a more complex organization and are involved in development regulations in ways that are not shared with the prokaryotes. Understanding the consequences of mutation in a eukaryote, such as the human, requires understanding of genetic organization in eukaryotes. The effects of interfering in normal gene action can be understood only if we know how gene action is evoked and represses, and how these processes may be altered by mutation. Therefore, research on the genetic organization and the analysis of mutant genes in eukaryotes has a high priority.

The culturing of somatic cells of mammalian species, including those of man, appears to be a promising way of making some of the comparisons, since it will make possible a variety of procedures that can be carried out relatively rapidly. The development of procedures for screening for mutants and for the genetic analysis of the mutations that occur has high priority.

(*2*) *Mutant genes in population*

The effect of an increase in mutation rate in germ cells is to increase the frequencies of less desirable genes in the population. The consequences of this would be some increase in the incidence of genetic disease and other inherited handicapping conditions in the population. Precise estimation of the change in incidence of disease requires detailed knowledge of the populational processes that take place, particularly what it is that maintains the current incidence of genetic disease. The process of elimination of mutant genes from natural populations is being studied by several investigators.

These problems are relatively simple in the case of mutant genes whose effects can be seen singly, but become complex in conditions that are brought about by substitutions at a number of genetic loci (polygenic or multifactorial characters). Most of the human disease with which we are concerned falls in this category. The assessment of the impact of mutation on the incidence of hereditary diseases of a more complex nature (e.g., diabetes) requires that there first be a better development of the concepts of how the normal genetic variability that underlies the variable expression of polygenic characters is maintained in natural populations. These studies need to be pursued at theoretical and experimental levels to furnish a better basis for understanding genetic studies on normal human populations, which in turn are needed to understand the effects of altering the mutation rate.

Studies are made on human populations wherever appropriate populations can be found. These must be populations that are well defined in terms of composition (minimal migration), and where record keeping makes it possible to link the various records that will enable investigators to make correlations useful in interpreting genetic effects. The purpose of these studies is to supply a basis for evaluating effects, rather than to supply directly a measure of the effects of increased mutation. These studies supply information for one of the key steps in estimating the consequences of increased mutation and therefore are given high priority.

(3) *Chromosomal Aberrations*

Work on chromosome aberrations involves a variety of organisms, including humans that have been exposed to significant radiation doses. Evaluation of cytogenetic damage in human populations requires the ability to estimate levels of damage at low doses and the ability to describe the consequences of aberration as these affect the normal distribution of genetic material to the functional germ cells. Work with mammalian species will show how these respond, quantitatively, and will serve to verify that the mechanical problems of genetic transmission are not different from those in organisms where more sophisticated genetic analysis is possible. Finally, wherever it is possible to study these processes in exposed humans, it is imperative to do so in order to verify the nature and level of human response to radiation.

In evaluating cytogenetic endpoints, there is a need for an understanding of the normal mechanisms of genetic transmission. The proper analysis of these processes must first be carried out in lower organisms, since it is only with a limited number of these that adequate methodology exists. Whenever possible, confirmatory studies should be made using mammalism species.

Chromosomal aberrations constitute a major class of human genetic disability. Aberrations of concern involve either rearrangements of segments of chromosomes (structural aberration) or changes in the number of chromosomes without significant change in their individual genetic content (numerical aberration). The genetic effect of the latter is abnormal development of individuals having the wrong number of chromosomes. The adverse genetic effects of structural aberrations are due mainly to the production of individuals of unbalanced chromosomal constitution in subsequent generations. The effect of imbalance, in either case, is abnormal development. In the majority of cases, this results in fetal death at relatively early stages of development. The consequences of chromosomal imbalance, in some cases, may be relatively trivial.

The kinds of information that are still needed in evaluating the consequences of chromosome damage include knowing how the different classes of structural aberration, primarily reciprocal translocation and Robertsonian translocation, are formed, relative to the germ cell stages at risk. The risk of Robertsonian transformation seems very low for male germ cells, but there is strong reason to believe that the conditions in the female germ cells (primary oocytes) may favor this kind of aberrations. This will require additional work with mammals, preferably with a species other than the mouse. The nature of the mechanisms of induction of numerical aberrations in an experimental insect (Drosophila) is known, but needs confirmation in mammals.

There appears to be a difference in the nature of the dose response for aberration induction between mammals and lower organisms that have been used to elucidate mechanisms. It is not known if this difference in response is due to some real biological difference, or is an artifact produced by comparing results in experiments where sampling methods are imprecise with those from experiments with precise sampling. Evaluation of low dose effects requires an answer to this question.

It is known that some kinds of rearrangements are not transmissible through the male, due to sterility. A more thorough analysis of the nature of such non-transmissible rearrangements is needed. More information is needed to relate the process of induction to the nature of the cell at risk in order to estimate the fraction of translocations induced in humans that would be non-transmissible.

(4) *Chromosome studies in human populations*

Observations are being made on the offspring of the atomic bomb survivors in Japan, to determine the aberrations that are detectable by current cytogenetic methods. These studies can be used in conjunction with studies in other organisms to verify the range of sensitivity of human germ plasm to cytogenetic radiation damage. In other studies chromosome damage in somatic cells of exposed humans is being examined. These kinds of studies will lead to an improved evaluation of the effects of germ cells in humans, through comparisons of germ cell and somatic cell effects.

Only limited observations have been made on normal human populations, where cytogenetic endpoints have been scored. More information is needed from systematic population surveys. Prospective surveys of pregnancies in a normal population are needed with diligent cytogenetic evaluation of all products, liveborn as well as aborted fetuses.

The collection of information from such surveys, to establish the level of cytogenetic defects in normal human populations and the consequences of these, will be greatly advanced by methods of applying pattern recognition techniques to human chromosome preparations. Continued support of efforts to develop and improve these techniques was high priority.

While it is well documented that radiation induces genetic changes in somatic as well as germ cells, the significance of these in somatic cells is largely unknown. The use of cultured lymphocytes from peripheral blood has been developed to provide an integrated biological estimate of radiation dose received from whole or partial body irradiation.

b. Studies with internally deposited radionuclides

Because of the greater precision of dosimetry, much of the work on genetic effects of radiation has employed external sources. Most of this work, especially on the mechanisms of mutation, is also directly applicable to radiation from internally deposited radionuclides. Research on the genetic effect of internally deposited radionuclides has been limited to those cases where specific questions relate to the properties of the radionuclide and/or the effects of its incorporation into the genetic material, or the effects of some specific radionuclide that may constitute a special occupational or environmental hazard.

For genetic effects, it is necessary to determine if a radionuclide incorporated into the genetic material produces mutation by its emitted radiation (e.g., beta radiation from tritium) or by its transmutation into another element. Work of this kind in bacteria has been supported in the past and currently is being supported in studies with higher organisms. Studies are being carried out in the mouse to evaluate the relative biological effectiveness of tritium beta radiation on mutation. Since tritium is a potential source of human radiation exposure, this work will provide a better basis for estimating human damage from the random incorporation of tritium in the body including that incorporated in the DNA. Studies at ORNL, LLL, and BNL are concerned with the genetic effects in mice of low exposures to tritium. Tritium is receiving emphasis due to its abundance and potential for release in all phases of the nuclear fuel cycle and in proposed fusion reactors.

While the deposition of plutonium and transplutonium elements in the gonads of mammals is very low (less than .1% of that in the blood) there is concern for the potential genetic effects of this deposition due to the densely ionizing alpha particle emissions of these radionuclides. Studies to delineate the genetic effects if any of plutonium have recently been initiated at ANL. This study is designed to determine uptake and retention coefficients for plutonium in the gonads and to determine the microdistribution of the dose within the gonad as well as the assessment of genetic damage by determining dominant lethal mutation rates and chromosomal aberrations. A new study at ORNL will use the specific locus method to further assess the potential genetic effects of plutonium.

At ITRI studies on the relative biological effectiveness of various types of radiation from either external sources or internally-deposited, liver-seeking radionuclides including transuranic elements, for the production of chromosomal aberrations in regenerating liver cells are in progress. Also included is the determination of the relative effectiveness of a uniformly and non-uniformly distributed dose. Also at ITRI, rhesus monkeys exposed to aerosols of $^{239}PuO_2$ are being studied to determine rates of chromosomal aberration in cultured lymphocytes at various times post-inhalation and over a wide range of lung burdens. This study relates to the reported increase in chromosome aberrations in lymposcytes of humans who accidentally inhaled plutonium from occupational exposures. However, the history of the workers regarding external radiation exposure complicates the interpretation of the cause of their chromosomal aberrations.

D. RECOVERY AND TREATMENT

Research is being conducted to develop effective safe methods of preventing or reducing the toxic effects of ionizing radiation in man. Research is directed toward the evaluation of therapeutic procedures including; (1) the administration of radioprotective drugs that activate molecular species produced by ionizing radiation in living tissues, and (2) the use of special agents or procedures that accelerate excretion or decrease absorption and reduce the risk associated with plutonium or other radionuclides deposited internally. Studies at ORNL are aimed at determining tissue levels of a phosphorothioate radioprotective compound (WR–2721) in normal and tumor-bearing animals of several rodent species. Preliminary data indicate that this compound is not readily absorbed by most solid tumors and that it selectively protects normal tissue in tumor-bearing mice. Research at the University of California at San Francisco is assessing the radioprotective properties of this compound in larger animal species. Both studies suggest that WR–2721 may prove useful as an adjunct in radiotherapy of cancer. Work at PNL has demonstrated that WR–2721 affords substantial protection to the gastrointestinal tract of mice exposed to high levels (1500R) of X-irradiation.

The currently accepted treatment for plutonium and many other radionuclides deposited in the body consists of chelation therapy possibly combined with early bronchopulmonary lavage if the radionuclide was inhaled. Past studies have shown that the chelating agent DTPA readily binds to plutonium and related radionuclides in the blood to form soluble complexes that are eliminated via the kidneys. The calcium salt of DTPA is approved for investigational use in humans and is used to treat accidental exposures of man. However, the calcium salt has been shown to be severely embryotoxic in mice and rats although at doses far above those used in clinical practice. Studies at PNL and the University of Utah have demonstrated that the zinc salt of DTPA, which is as effective as the calcium salt, is less toxic, and can be chronically administered safely over prolonged time periods. Thus, research is now in progress to develop the most effective therapeutic regimes for zinc DTPA and develop the necessary toxicity information relative to its possible use for therapy in man.

While the current therapeutic regimes utilizing DTPA removes a variable percentage of the internally deposited radionuclide, its efficacy in removing plutonium and other radionuclides deposited in bone and liver is limited. Several approaches to overcome this limitation are being investigated. The first of these is the synthesis of new chelating agents with a higher degree of specificity and/or a greater solubility in lipids. Studies at the University of Utah are investigating the efficacy and toxicity of multi-heteromacrocyclic molecules synthesized at the University of California at Los Angeles. These compounds can shape themselves to the actinide ion to provide a very high level of specificity of chelation. Another approach developed at ANL is the investigation of the efficacy of DTPA encapsulated into lipid materials prior to their administration to increase the entry of DTPA into the cell. Still another approach is to develop repository forms of zinc DTPA to provide chronic or continuous chelation therapy. Investigation of a technique has now begun at the University of Pittsburgh in which mixed ligand chelates will be administered separately, and are expected to bind plutonium in such a way as to permit passage across membranes. The administration of two separate compounds will be required as opposed to the classical approach of administration of a single agent. Screening techniques to test a large variety of compounds will be undertaken in vitro and the promising compounds tested in vivo in rodents.

Studies at New York University have shown that calcium DTPA is more effective in removing Am-241 deposited in the skeleton from the juvenile baboon as compared with the adult. Similar therapy in a human juvenile was surprisingly effective in reducing skeletal and liver depositions of Am-241 acquired several years ago in an accident.

As inflation is the most prevalent mode of exposure in accidents with nuclear materials and standard chelation therapy is relatively ineffective in removing inhaled materials, particularly if they are relatively insoluble, efficient therapy for inhalation deposition is needed. Bronchopulmonary lavage therapy which consists of flushing or washing the lung with physiological saline solution has been systematically evaluated in beagle dogs at ITRI. Both the efficacy of the removal of the inhaled radionuclide and the safety of the technique are being evaluated. With current methods the technique is effective in removing about 40 percent of the inhaled material. Methods to increase the efficacy of removal and to understand the factors responsible for variations in efficacy are underway. The successful development of this technique in dogs has led to the application of the technique to treat one case of an accidental inhalation exposure to plutonium in a man. Also, some of the techniques developed in dogs have led to the adaptation of a single lumen lavage technique for the successful lavage of infant humans for alleviation of the symptoms of cystic fibrosis and other pulmonary diseases. The efficacy of DTPA administered by inhalation rather than injection is being investigated at PNL.

In addition to evaluating the efficacy of therapeutic techniques in removing deposited radionuclides, studies are underway at PNL and ITRI to evaluate the efficacy of these therapeutic techniques in reducing the incidence and severity of biological effects. It is essential to recognize that the reduction in the body burden by therapeutic techniques may or may not proportionately reduce the biological consequences. Thus, animals treated by chelation therapy and bronchopulmonary lavage are being observed to determine the efficacy of these techniques in reducing the biological effects.

Part IV. Summary and Recommendations for Future Research

The important nuclear technologies are (1) Non-Breeding Fission Reactors utilizing the uranium fuel cycle, (2) High Temperature Gas-Colled Reactors which utilize the thorium fuel cycle to produce fissionable high specific activity uranium, (3) the Light Water Self-Sustaining Reactors which utilize the thorium fuel cycle, (4) the Liquid Metal Fast Breeder Reactor and possibly other types of breeder reactors which produce large amounts of plutonium, and (5) Fusion Power Systems as Controlled Thermonuclear Reactors as well as Laser Fusion Reactors.

Each of the converter and breeder reactor systems requires mining of uranium or thorium ores, extraction of fissionable material from these ores, fabrication of fuel elements, the use of this fuel in nuclear power reactors, the reprocessing of fuel, transportation, and ultimate disposal of radioactive waste. Each stage of the fuel cycle presents potential hazards to occupational population groups and potential hazards to the general population from the low-level routine releases, or from accidents which may occur at particular stages of the nuclear fuel cycle.

The major health hazards to man from present or future nuclear technologies are those involving radiation exposure either from external sources or from radioactive materials (radionuclides) deposited internally. These radioactive materials are primarily the large amounts of fissionable materials that are utilized by or recovered from both non-breeding and breeding types of reactors, fission products, and activation products of fuel or structural materials used in both fission and fusion reactors.

While our understanding of the short-term effects of high doses of radiation from these materials is adequate, a major gap in our knowledge is the long-term consequence of acute and chronic exposure to low levels of radiation.

Future nuclear technologies (e.g., breeder reactors) will both use and generate large quantities of toxic actinide elements (plutonium, americium, curium, etc.) that emit densely ionizing radiation for which the health consequences are not adequately defined, but which might include lung cancer, bone cancer, and possibly liver cancer. Growth in application of current and future nuclear technologies is critically dependent on obtaining reliable quantitative information on the health effects of these radionuclides, whether internally deposited (alpha and beta emitters) or causing external exposure from their penetrating emissions (beta-gamma emitters). Neutron and gamma exposures are potential hazards in the immediate proximity to operating reactors. The following objectives outline the scope of the current and future health related research necessary for the development of these technologies:

Objective I.—Identify and measure the spectrum of radioactive and non-radioactive pollutants associated with the uranium and thorium fuel cycles. This is composed of three research areas.

1. Identify and measure the spectrum of particulate and gaseous aerosols associated with work cycles and ore-handling operations in uranium and thorium mining.
2. Identify and measure the gaseous, liquid, and particulate effluents from milling and other processes involved in uranium, thorium and plutonium extraction, separation, processing, and waste storage.
3. Identify and measure the radioactive and non-radioactive agents in mine tailings that are hazardous and may cause human exposure.

Large scale use of non-breeding, electric-power producing reactors will require greatly increased mining and milling of uranium ores. It is expected that future ore reserves will come from deeper mines with increased potential for exposure of workers to radon, radon daughters, and a variety of gaseous organic and inorganic pollutants from mining machinery. Interaction of radioactive and non-radioactive pollutants can increase the human risk to debilitating respiratory diseases as well as to lung cancer. It will be necessary to identify the spectrum of radioactive materials associated with the mining and milling operations as well as to monitor those materials as a routine part of the operations. It will also be necessary to identify and measure the radioactive gaseous, liquid, and solid particulate agents involved in the fuel extraction, fabrication, reprocessing, and waste storages of the fuel cycle.

Objective II.—Determine the metabolism and biological fate of alpha-emitting actinide elements and of the specific fission and activation products associated with advanced nuclear technology. This involves five project areas.

1. Determine the mechanism and kinetics of incorporation, metabolism, deposition, and turnover of the actinide elements (uranium plutonium, curium, americium) in the various chemical forms encountered in the nuclear fuel cycles in human and experimental animal populations.
2. Determine the mechanisms and kinetics of deposition and turnover of fission and activation-roduct radionuclides.
3. Determine the influence of age, sex, metabolic, state, diet, prior disease, other internal contaminants, and other physiologic factors on the metabolic behavior of relevant radionuclides.
4. Determine the metabolism of the actinide elements for conditions of low level continuous exposure.
5. Determine the metabolism of mixtures of actinides that will commonly be encountered in the nuclear fuel cycle.

The ultimate evaluation of health risk must be in terms of the absorbed radiation dose which often differs markedly from the exposure dose. This information must be derived from detailed measurement and understanding of the mechanisms and kinetics of the incorporation of inhaled, ingested, or injected radioactive materials as well as the translocation, deposition, turnover, and excretion of actinide elements as well as fission and activation products to which man might be exposed.

Emphasis will continue to be placed on the biological behavior of radionuclides following inhalation. Since exposure to radioactive hazardous pollutants can be indirect via water to soil to man's food chain, it is important to evaluate this route of transport to man and to determine the hazards of ingested radionuclides. Inhaled radionuclides cleared from the lungs may also be absorbed from the gastrointestinal tract.

Metabolic data will be obtained from human exposure cases where possible but most of the information will be derived from comparative studies using model experimental animals. Such metabolic data are needed to accurately compute the absorbed dose, which when evaluated with effects permit reliable predictions of risk to people.

Objective III.—Evaluate the short- and long-term carcinogenic, pathophysiological, teratogenic, and mutagenic hazards of the fuel cycle elements in formal, susceptible, and stressed populations. This involves three major program areas.

1. Conduct epidemiological and clinical studies in selected human population groups to evaluate the long-term hazards of exposure to radiation both from external sources and from internally deposited radionuclides.

2. Correlate the long- and short-term effects of the various actinide elements with the deposition levels in specific organs in exposed human and animal populations.

3. Correlate the long- and short-term effects of the various fission and activation products with the deposition levels in specific organs in exposed human and animal populations.

The major health hazards associated with the nuclear fuel cycles will be latent pathophysiological effects which produce debilitating respiratory and systemic organ disease as well as carcinogenic, mutagenic, and teratogenic effects. Although evaluation of these effects at relatively high exposure levels is quite advanced, much more information is needed to provide reliable quantitative estimates of the health risks from low level continuous exposure to the actinide elements such as plutonium, americium curium, and the higher actinide series produced in advanced non-breeder reactors. In addition, much more information is required to assess the synergistic action of radioactive and non-radioactive pollutants in production of pathophysiological damage as well as carcinogenic, teratogenic, and mutagenic effects in the occupational or general population.

Because the degree of exposure to man has not often been much less than exposure levels where biological effects have been observed in experimental animals, it is necessary to extrapolate from higher dose experiments in animals to lower dose experience in man. There is inadequate information in this area.

There is very little information on the biological effect of chronic exposure to actinides. Most of the previous experimental work related to late effects used single exposures while the late effects associated with human population will be of chronic nature. Experimental data using animal models are urgently needed and studies of this nature have recently been initiated.

Objective IV.— Determine the processes of damage, repair, recovery, protection, and amelioration in biological systems exposed to hazardous agents associated with nuclear technologies. This is composed of four research areas.

1. Identify the mechanisms by which living systems repair and recover from lesions induced by exposure to radiation, and assess the role of the mechanisms in human recovery from exposure to radiation.

2. Identify the biochemical lesions induced by interaction of biological systems with radiation in order to identify susceptible population groups, provide early indicators of injury, and guide the development of protective and remedial therapies.

3. Develop and test methods to enhance normal recovery and repair mechanisms, and develop protective remedial therapies.

4. Develop and test devices and procedures to protect against the effects of radiation, particularly in the occupational setting.

The information developed under Objective II will be used in the development of remedial methods to reduce or remove internally deposited redionuclides arising from nuclear technologies; when developed, these same techniques may also provide safe decorporation therapy for nonradioactive heavy metal poisoning (cadmium, mercury, lead).

Objective V.—Determine the Future Health Hazards Associated with Fusion Reactors.

The major potential health problems currently envisioned for most of the fusion technologies revolve around tritium, neutron activation products and magnetic fields. If the hybrid fusion-fission concept is employed, the actinide elements could be of concern.

The tritium involved in fusion reactors will be present as the gas and the amount will be large. Although there is large literature on the biological effects of tritium as tritiated water, additional information is needed on the effects of tritium gas.

The actual activation products which will be produced will depend on the structural materials ultimately used. Although these have not been fully defined, it is expected that aluminum, boron, niobium, stainless steel, titanium and vanadium are likely to be important constituents.

The use of large magnetic fields represents an area unique to fusion reactors. Although there is a large body of literature on the biological effects of magnetic fields, the quality of the information is inadequate to guide the setting of standards. Therefore, a program is being initiated to investigate the biological effects of magnetic fields under a wide-spectrum of conditions.

It will be necessary to periodically evaluate the potential health effects associated with fusion systems. The Laser/Fusion Safety Committee which has been established within ERDA is expected to contribute to the identification of possible problems so that the health effects studies can keep pace with the development of the technology.

SUMMARY

The research effort on the potential health effects of current and projected nuclear technologies has increased significantly over the past 10 years. Most recently the potential health effects of transuranic radionuclides have been given greatest emphasis. The status of the current research is continuously evaluated and problems emerging from developing technologies are included as soon as possible. Several review groups assist BER staff in directing the emphasis of the research. Research has been initiated to adequately answer the objections I–V outlined previously. Although much of the research has been initiated over the past 5 years, certain critical problem areas such as mixed oxides, plutonium and sodium aerosols, plutonium nitrate, and chronic exposures are just now being addressed. Work on combined insults such as plutonium inhalation and another pulmonary insult (i.e, cigarette smoking) is in very early stages of investigation.

Many of the low dose level studies that have been initiated will require several years to complete. It is also certain that, as they are identified, other needs will be given high priority as alternate reactor systems emerge. Thus, while it is anticipated that funding for research on the health effects of nuclear technology will not increase markedly, funding of projects to provide the answers to the stated objectives will be continued.

NON-IONIZING RADIATION*

*(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Physical and Technological Studies

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 In-House (Positions)	7508	18,188		N/A			N/A	5795			36,034	7367
1969 Extra-Mural (Funds) Total Funds	7615	17,985		N/A			N/A	7274			39,619	7373
1970	7742	18,570		N/A			N/A	7548			40,279	7299
1971	7861	18,365		N/A			N/A	7390			40,080	7210
1972	9414	18,166		N/A			N/A	8169			40,650	8049
1973	11,152	21,024		N/A			N/A	8510			41,140	8200
1974	12,492	22,750		N/A			N/A	8870			42,630	8950
1975	12,627	31,254		N/A			N/A	14,930			23,131	12,199
1976	11,282	12,112		463			2561	14,062			25,170	6200
1977	12,070	11,838		500			1900	17,440			24,574	6434
Est. 1978	12,438	12,330		1045			2660	13,972			26,221	6854

applies to all years

ENVIRONMENTAL STUDIES

NUCLEAR RELATED RESEARCH

Nuclear related research has undergone reprogramming and redirection over the last two years which has led to changes in emphasis but no diminution in the overall program. In general, research on the transport and fate of intermediate-lived fission products has been curtailed as a large data base exists. Similar reductions in chronic irradiation experiments have occurred as major objectives have been met. Concurrently, however, increasing emphasis has been placed upon the environmental behavior of the transuranium elements, the radioecology of uranium, certain very long-lived fission products and radionuclides associated with controlled thermonuclear reactors.

Two programs formerly classified as nuclear have been reclassified as multitechnology. These involve ecological effect of cooling systems (thermal) and research related to offshore power plant siting.

ENVIRONMENTAL STUDIES OF PLUTONIUM AND OTHER TRANSURANIC ELEMENTS

In fiscal year 1974, the BER program in environmental research for the transuranium elements consisted of land, freshwater and marine research on the biogeochemistry of plutonium, plant uptake of plutonium and americium under greenhouse conditions and limited ecosystem transport.

In fiscal year 1975, major aquatic and terrestrial ecosystem studies were begun at locations known to have been contaminated above fallout background levels. Food chain studies related to pathways to man were expanded to include field studies of plant uptake under agricultural conditions and ruminant feeding studies to evaluate milk and meat contamination. Soil chemistry, plant uptake, and ruminant feeding studies with curium and neptunium were also started. An ongoing study in the Marshall Islands in marine sciences has been supplemented by land and freshwater investigations to determine the fate of transuranium elements in Enewetok Atoll.

In fiscal year 1976, support was increased for all of the foregoing areas, and additional work was begun to develop information on the long-term behavior of the transuranium elements in the environment. Three approaches are underway:

(1) The identification of soil and sediment chemistry parameters which affect the mobilization of the transuranium elements.

(2) Long-term agricultural experiments to determine effects of weathering and aging upon availability of these elements.

(3) Study of the behavior and availability of certain elements which have analogous chemical properties to transuranium elements and which have been undergoing weathering and aging in soils through geologic time.

In fiscal year 1977, the program elements have continued with increases in analytical support to some programs and the completion of two projects.

RADIATION EFFECTS OF CHRONIC EXPOSURES ON ECOSYSTEMS AND OTHER STUDIES

While the transuranium research was expanding, some of the support for older nuclear research areas was being reduced. Chronic radiation studies of ecosystem were reduced to maintenance levels as the major objectives of that program were met. Studies involving fission products with short and intermediate half lives were curtailed except where major questions still need to be answered (e.g., persistence of ^{137}Cs availability to food chains in the Southeastern U.S., ^{55}Fe inputs to marine systems and their subsequent transfer through the marine food webs). High altitude sampling programs for weapons debris and development of the Atmospheric Release Advisory Committee (ARAC) have maintained essentially level funding in atmospheric sciences.

New programs dealing with certain fission products have expanded over this same period of time. The long-lived ^{129}I and ^{99}Tc are presently under investigation in laboratory and field studies. The absorption and bioaccumulation of tritium gas in soils and plants and the transport of triliated water from rivers to estuaries and across the continental shelf are other areas which are receiving attention. New programs were initiated in fiscal year 1976 on the radioecology of the higher specific activity species of uranium, and on the ecological aspects of uranium tailings and their stabilization.

NUCLEAR ORIENTED RESEARCH ACTIVITIES WITHIN THE PHYSICAL AND TECHNOLOGICAL PROGRAM

The nuclear related research activities within the Physical and Technological Program addresses five major research areas. These research categories are outlined below with a brief description of the program content.

Radiological physics research.—This research is concerned with determining the physical parameters that govern radiation interaction within biological systems. This information is required so that theories or models which describe and predict radiation effects can be formulated. Although our physical understanding of radiation interaction is far from complete, knowledge is sufficient to permit an aggressive effort to develop descriptive theories of radiation action. Consequently, the radiological physics research program is decreasing to permit an expansion in the development of theories of radiobiological action.

Development of theories of radiobiological action.—Physical parameters such as molecular excitation, free radical formation, and their spatial and temporal distribution serve as the foundation upon which models of biological effects are developed. The results of these studies have recently impacted two important areas. Analysis of biological effects at low exposures for high LET radiation is providing a new insight into low-dose radiation effects. The second area in which these studies are finding application involves the planned use of new radiation beams (heavy ions and negative pi mesons) for radiation therapy. The theories are important in estimating the effectiveness of various beam configuration and treatment plans.

Neutron and gamma ray dosimetry research.—These studies are directed toward development of improved techniques, procedures and systems for neutron and gamma dosimetry. Emphasis is placed on development of field systems for measurement of low-level radiation with the objective of achieving improving capability for the determination of nuclear power plant and reprocessing plant emissions. Neutron dosimetry research continues to merit primary attention.

Plutonium and other aerosol research.—The objective of these studies is to develop improved methods and technology for the measurement of plutonium, both in vivo and in situ and for the measurement and characterization of other radioactive particulates. A major effort is underway to improve our capability for measuring plutonium deposition in the lung. A second program is directed toward achieving an enhanced field measurement capability for the quantiative determination of plutonium in soil.

Radiation instrumentation research.—This program is directed toward development of improved radiation detectors. Current effort involves a continuing materials research on germanium in an effort to develop large volume radiation detectors. A concurrent effort on other potentially useful solid-state materials is underway to achieve a high atomic number, room temperature semi-conductor radiation detector.

MEDICAL DIAGNOSTIC THERAPEUTIC

The funds identified in this column represent the Biomedical Applications within the program Life Sciences Research and Biomedical Applications under the Assistant Administrator for Environment and Safety.

Medical applications of nuclear technology

The objectives of this research are to determine new uses of radiation, radioactive and enriched stable isotopes for the diagnosis and treatment of human disease.

The following elements are representative of the Program.

Research in nuclear medicine is being redirected so that the research not only addresses the needs of the medical community in general but also focuses more sharply on the ERDA energy-oriented mission, i.e., the development of new techniques to detect early signs of disease related to energy effluents.

Recent advances achieved in nuclear medicine instrumentation dictate a shift in the direction of this research.

Emphasis on new radionuclides and radioactively labeled agents is shifting toward the development of positron-labeled radiopharmaceuticals. These agents, used in combination with the new instrumentation, will permit actual localization in depth (tomography) of lesions and opens up a new field of organ function studies. A similar change in emphasis has been made already in the clinical nuclear medicine research and has yielded significant results. New techniques for the safe and rapid detection of blood clots in the lung and elsewhere in the body have been developed. New radiopharmaceuticals for the detection of tumors and metastatic lesions are being tested in the clinic. Non-invasive techniques for the early detection of heart disease and the quantitation of damage following heart attacks show considerable promise for patient management and in evaluation of patients for cardiac surgery.

A new center for emergency treatment of radiation accident victims is now operational in Oak Ridge, Tennessee. This unique facility will also serve as a central facility for the training of physicians and paramedical personnel in the management of patients exposed to harmful doses of ionizing radiation.

Research in radiotherapy is mainly focused on the use of heavy particles. These particles have theoretical advantages in their effectiveness to destroy tumor cells. A major effort is being conducted at the LBL Bevalac high energy, heavy ion accelerator to explore the actual usefulness of these particles. This is a cooperative effort with the National Cancer Institute.

Research on the production and use of stable isotopes

The objective of this effort is to increase the production of enriched stable isotopes of carbon, oxygen and nitrogen and the development of new uses for these isotopes. Their applications in medical, biological and environmental research areas appear most promising. Application of stable isotopes under conditions where radiation is undesirable, such as pediatrics or mass screening in preventive medicine, are considered of great interest. Excellent promise was demonstrated in the use of stable isotopes to trace the movement of gases released from, for instance, fossil fueled power plants. These studies could yield important information on how pollutants are dispersed in the environment and reach man.

Strong interest by the National Institutes of Health has resulted in the establishment of a jointly supported National Stable Isotope Resource at the Las Alamos Scientific Laboratory.

Medical devices

Two implantable versions of the bench-model of the artificial heart were recently completed and are being tested in the laboratory. Subsequent animal testing is planned for the near future to evaluate the physiological acceptability and system performance. Preliminary experiments in animals with an electrically driven pump have demonstrated the feasibility in principle of total heart replacement by a mechanical device. Major problems in both the engineering and biocompatibility aspects of the device have yet to be solved.

CRITERIA AND/OR STANDARDS DEVELOPMENT

This program supports and provides the means for the development of ERDA safety standards, criteria, and guidelines. These standards, in turn, provide a backbone on which operations can be run in an orderly, efficient and safe manner. They also serve as the yardstick against which performance can be measured. The program assures that the specified procedures, steps, operating limits, functions, etc., are based on sound logic, accepted practices, supportive analytical work, and data research. This eliminates the possibility of reliance on untested methods or ideas.

SURVEILLANCE OF FACILITIES AND SITES (MONITORING AND/OR SURVEILLANCE)

This program supports efforts aimed at the determination of hazards and their level of severity to people, property and the environment. Through the use of improved procedures, hardware, systems, and monitoring techniques, a broad spectrum of hazardous elements is isolated and measured, and the existing and potential impact is evaluated. In addition, we maintain an Aerial Measuring System (AMS), formerly called Aerial Radiological Monitoring System (ARMS), is a continuing program for remote sensing data acquisition. The capability of remote sensing of naturally occurring radiation in the environment and of contamination whose type and amount are influenced by activities of man is expected to continue This capability is ERDA's primary emergency response to the loss of radioactive sources or large accidental releases of radioactivity or other hazardous materials, should such losses or releases occur. Rapid evaluation of the consequences of an accident situation is possible through detailed documentation of prior base-line surveys of ERDA and licensed nuclear facilities.

These base-line surveys are conducted by high technology personnel using a wide assortment state-of-the-art remote sensing equipment designed for rapid installation on a mix of aircraft (both fixed wing and helicopters). In addition to gaining the base-line data, these surveys provide that operational experience which is essential for the constant improvement of personnel expertise and equipment performance. This evolutionary process has allowed for the application of many remote sensing techniques to the monitoring of nonnuclear energy effluents and constituents.

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. EPA was created in 1970 and given responsibility for setting generally applicable environmental radiation standards. To date, the only radiation standards promulgated under this authority has been Title 40 CFR 190 "Environmental Radiation Protection Standards for Nuclear Power Operations," which pertains to nuclear facilities involved in the nuclear power industry and which has imposed some controversial restrictions on nuclear power plants and fuel reprocessing plants.

The responsibility and authority of the now defunct Federal Radiation Council, to make recommendations to the President concerning radiation protection standards for use by Federal agencies was also transferred to EPA but, as yet, EPA has not submitted any new recommendations under this authority.

EPA has since been granted statutory authority to regulate radioactive materials other than those regulated by the NRC under the Atomic Energy Act (AEA), in liquid effluents and surface water (by the Federal Water Pollution Control Act) and in ground water and drinking water (by the Safe Drinking Water Act). The question of EPA's authority to regulate radioactivity in liquid effluents from facilities that are regulated by NRC under the AEA was contested in litigation and the Supreme Court held (COPIRG v. Train) that EPA did not have such regulatory authority under the provisions of the Federal Water Pollution Control Act.

In 1975 the Atomic Energy Commission was abolished and its regulatory authorities under the Atomic Energy Act were transferred to the newly created Nuclear Regulatory Commission (NRC). AEC's research development and operational functions were transferred to the newly created Energy Research and Development Administration.

The changes described above have not substantially changed ERDA's research, development and operational functions in the radiation area. However, there have been some changes as a result of the transfer of FRC's responsibility to EPA in regard to the development of Federal radiation standards. These changes have resulted in some confusion regarding responsibilities for setting radiation protection standards. The confusion appears to lie primarily in the area of EPA vs. NRC authority for promulgating regulations pertaining to radioactivity emanating from facilities regulated by NRC. This confusion has led to some litigation and one Supreme Court decision (*COPIRG* v. *Train*).

Question 2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

Answer. There are routine contacts between ERDA's field offices and state groups in those states where ERDA operates nuclear facilities. These contacts involve the exchange of information including routine reporting and discussion of effluent and environmental monitoring data collected in or in the vicinity of ERDA facilities primarily by ERDA contractors but in some instances by the states as well. State and regional groups visit ERDA facilities and are thoroughly apprised of operations at ERDA facilities that are conducted or planned and may be of interest to state and regional groups. Since the states have no regulatory jurisdiction over radioactivity at Federal facilities, there has not been any confusion concerning their respective responsibilities.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. There is one area in which the present regulation of radiation programs could be improved to avoid the confusion that exists regarding responsibilities for esablishing radiation standards. We believe it is appropriate that generally applicable environmental radiation standards, based on protection of the health and safety of the public, should be developed and promulgated by the Environmental Protection Agency. However, since long established policy in nuclear energy research, development and operations require that radiation exposure to the public, the environment, and radiation workers be maintained as far below prescribed standards as practicable, the determination of practicability should be the responsibility of the agencies responsible for developing the nuclear technology and regulating its commercial application. This is an important distinction since the application of nuclear energy is one of if not the only industrial application of technology that is totally regulated beginning with site selection, facility design, and construction and continuing on through operation, decontamination and decommissioning and disposal. Decisions on what is practicable require extensive knowledge and detailed evaluation of the design and operation of the nuclear technology and the costs and effects of alternate methods for containing and controlling radiation exposure within and outside of the facility. Such decisions cannot be based solely on environmental or on economic considerations and would require unnecessary costly and counterproductive regulatory authority if more than one agency has responsibility for such decisions. The responsibilities for setting radiation environmental standards for determining how far below such standards additional controls are practicable, is separable and should be kept separate. Clearly, the promulgation of regulations governing both environmental radiation protection and regulation of nuclear facilities should be subject to review by all agencies concerned, as is presently the case. However, while there is need for clearer definition of these responsibilities than presently exists, it is not clear whether legislation is necessary to accomplish this.

Question 4. What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal radiation agency?

Answer. Proposals to consolidate all Federal regulation activities into one Federal radiation agency do not appear to be workable. It is appropriate that the responsibilities for radiation activities be handled in the same way as the various responsibilities for handling of other potentially hazardous materials. Specifically, the responsibiliy for public health, environmental protection, and energy technology development aspects of radiation and radioactivity are appropriately assigned to those departments and agencies that have similar responsibilities with regard to other public health, environmental or energy-related matters. There appears to be no sound rationale for treating Federal radiation activities any differently than other potentially hazardous activities.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH,
Rockville, Md.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of May 26, requesting information about NIOSH research and technical assistance programs in the area of radiation. We do not have authority under the Radiation Control for Health and Safety Act of 1968 (P.L. 90–602), which concerns the public health aspects of radiation emissions from electronic products. We do, however, have an active program under authority of the Occupational Safety and Health Act of 1970 (P.L. 91–596). This letter will respond to the specific questions you raised in your letter. In addition, we are enclosing a list and brief description of our radiation projects for the years specified.

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. Prior to passage of the Occupational Safety and Health Act of 1970, the predecessor organization of NIOSH operated under the general research authorities of the Public Health Service Act. Between 1968 and 1971 a small portion of our resources were devoted to the radiation effort. Following passage of the Act, NIOSH was given specific responsibility to develop recommended standards for exposure to a broad range of occupational hazards, including radiation.

These recommended standards are transmitted to the Occupational Safety and Health Administration (OSHA) in the Department of Labor (DOL), which is responsible for setting and enforcing the standards.

In fiscal year 1972 NIOSH established a Radiation Section in what is now the Division of Biomedical and Behavioral Science. The section performs research at our laboratory in Cincinnati, Ohio on the biological effects of radiation. Research areas include ionizing radiation sources subject to OSHA regulation (machine-produced radiation and naturally-occurring radio-nuclides), as well as non-ionizing radiation sources (microwave, radio-frequency (RF), laser, visible, ultraviolet, infrared, sound and ultrasound). Other radiation research is conducted by NIOSH in the areas of field studies, hazard evaluations, control technology, and personal protective equipment and instrumentation development. Additionally, our staff provides training and technical assistance in the radiation areas to personnel of other organizations.

Criteria documents recommending standards for occupational exposure have been developed for noise and ultraviolet radiation. Documents planned for fiscal year 1977 through 81 include radiofrequency and microwave radiation, infrared radiation and ultrasonic radiation. In addition, a criteria document will be developed for welding and brazing processes, including radiation exposure aspects. Planned for transmittal to OSHA beyond fiscal year 1981 is the visible radiation criteria document.

Question 2. Would you please describe the nature of the contracts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and Federal agencies?

Answer. NIOSH has interacted on radiation matters with other Federal agencies, including the Bureau of Radiological Health and the Bureau of Medical Devices of the Food and Drug Administration, the National Cancer Institute and the National Institute of Environmental Health Sciences of the National Institutes of Health, the Occupational Safety and Health Administration and the Bureau of Labor Statistics of the Department of Labor, the Atomic Energy Commission (and its successors), the Environmental Protection Agency, the Electromagnetic Radiation Management Advisory Council of the Office of Telecommunications Policy, the Department of Defense, the Federal Aviation Administration, the National Bureau of Standards, the Internal Revenue Service of the Treasury Department, the Mine Enforcement and Safety Administration, and the National Academy of Sciences.

Although we are not required to coordinate our work with states, NIOSH has worked cooperatively with state programs whenever possible. In FY 75, we conducted a study to identify potential problems associated with the use of non-medical radiation sources under jurisdiction of the Occupational Safety and Health Act. The study was based on reports of radiation surveys and accidents in nine states, and could not have been performed without state cooperation. We also send a representative to the annual conference of State Radiation Control Program Directors.

Additional interaction with state groups regarding radiation matters is evident from the list of our radiation projects (appended). To the best of my knowledge, there is no confusion concerning respective responsibilities between state agencies and NIOSH (or other Federal agencies).

We also have worked with universities, trade associations such as the American Welding Society, organized labor, the International Microwave Power Institute, the American Industrial Hygiene Association, the Health Physics Society, the American Public Health Association, the American Conference of Governmental Industrial Hygienists, the Institute of Electrical and Electronic Engineers, the American National Standards Institute, and similar professional groups, radiation equipment manufacturers, and foreign and international agencies, such as the Ministry of Health and Welfare in Canada, and the World Health Organization.

Question 3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. NIOSH maintains a general awareness of the activities of other agencies, and feels that, despite the fact that we are not aware of any deficiencies in the regulation of radiation programs, increased coordination among Federal radiation programs would be useful. As an example, the Electromagnetic Radiation Management Advisory Council (ERMAC) of the Office of Telecommunications Policy has established the Biological Effects of Nonionizing Electromagnetic Radiation Committee (BENER) which reviews and coordinates microwave and radiofrequency biological research activities in Federal agencies. Through periodic meetings, all agencies are briefed on ongoing programs to minimize duplication of effort and maximize interagency cooperation.

Within NIOSH, funding for radiation programs has increased steadily since the Radiation Section was formed. The present funding level is appropriate for in-house studies considering existing personnel resources. We have scheduled criteria documents that should provide the basis for complete health standards for the most important occupational exposures to radiation.

Question 4. What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal radiation agency?

Answer. Although NIOSH would support further coordination among Federal radiation activities (as outlined Question 3), we would foresee certain problems in consolidating all such programs in a single agency. The primary problem would be that the existing radiation programs have been established for different purposes in response to different Congressional mandates. NIOSH focuses on an integrated occupational safety and health program to protect workers; for example, radiation in the workplace can generate toxic gases. Ultraviolet radiation from a welding torch can generate toxic quantities of ozone and oxides of nitrogen. To have one agency responsible for the gaseous environment, while another agency is responsible for the radiation environment could result in failure to recognize and correct a potentially dangerous situation. NIOSH believes it is more important to use a broad spectrum of scientific specialties to protect workers on a functional or total basis than to separate the disciplines and try to protect workers on a piecemeal, or hazard-by-hazard basis. Also, since workers are exposed simultaneously to chemical and physical hazards (including radiation), which may produce additive or synergistic effects, we believe that less protection would be afforded employed men and women if all radiation programs were put in one Federal agency. The answer to this question reflects the views of NIOSH and not necessarily those of the Department.

Sincerely yours,

EDWARD J. BAIER, *Deputy Director.*

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Fiscal year—Category and brief description	Man-years	Extramural funds	Total funds
NONIONIZING RADIATION PROJECTS			
1968—Monitoring (laser) Survey of laser installations to evaluate potential laser harzards.	2.0	0	25,000
1968—State/Federal liaison (laser) Survey of laser installations to determine need for State regulatory control.	2.0	0	25,000
1968—State/Federal liaison (microwave) Review of health programs, survey techniques and instrumentation employed in microwave hazard evaluations.	1.0	0	25,000
1969—Monitorng (laser) Survey of laser installations to evaluate potential laser hazards, publish results of survey.	2.0	0	30,000
1969—State/Federal liaison (laser) Survey of laser installations to determine need for State regulatory control; publish results of study.	2.0	0	30,000
1972—Criteria and/or standards development (UV) Award contract to Franklin Institute Research Laboratories to develop UV criteria document; publish document (HSM 73-11009).	.5	20,000	30,000
1972—Monitoring (ultrasound) Award contract to determine potential hazards and select survey instrumentation.	.4	40,000	50,000
1972—Monitoring (UV, RF) Surveys of RF sources in forest products industry, development of UV monitor (CBS); Interagency Agreement (IA) with NBS to provide calibrated lamps for UV facility.	.3	46,000	56,000
1973—State/Federal liaison (all types) Development of nonionizing radiation safety course for OSHA industrial hygienists; 2 presentations of course.	1.0	0	15,000
1973—State/Federal liaison (microwave) Development of microwave calibration system to calibrate OSHA microwave instruments.	.1	0	10,000
1973—Monitoring (UV) Monitor UV meter (CBS) contract; develop test procedures for evaluation of meter.	1.5	5,000	33,650
1973—State/Federal liaison (RF/microwave) Review of current OSHA microwave standard especially below 300 MHz; evaluate need for standard for pulsed electromagnetic radiation.	1.65	0	58,065
1974—State/Federal liaison (microwave) Development of microwave calibration system to calibrate OSHA microwave instruments.	.2	0	10,000
1974—Other (training) (all types) Presentation of nonionizing radiation safety course.	.3	0	4,000
1974—Health effects (UV) Award contract for UV ocular effects (300–400 nm).	1.2	120,000	134,500
1974—Monitoring (UV) Award new UV meter contract (KA), establish calibration facility, obtain standard detectors from NBS; publish UV (CBS) report.	1.3	101,460	138,460
1974—Monitoring (RF) Award IA to NBS for RF instrumentation; survey of industrial RF applications.	1.9	40,500	83,500
1975—State/Federal liaison (microwave) Development of microwave calibration system to calibrate OSHA microwave instruments.	.2	0	10,000
1975—Other (training) (all types) Development of package training course and manual on nonionizing radiation safety; presentation of 2 courses.	.5	70,000	80,000
1975—State/Federal liaison (laser) Initiate IA with Army to classify lasers according to draft OSHA laser standard; technical request from OSHA Office of Standards.	.4	4,000	13,800
1975—Health effects (UV) Monitor UV ocular effects contract.	.7	0	14,050
1975—Health effects (RF) Initiate IA with USAF School of Aerospace Medicine to study biochemical changes due to RF exposure, establish need for phantom modeling work.	.8	50,000	71,560
1975—Health effects (visible) Organize symposium to identify potential safety and health hazards from decreased lighting levels; define research needs; publish symposium proceedings (75–142).	.4	0	19,800
1975—Monitoring (RF) Surveys of industrial RF sources; initiate IA with NBS to design RF synthesizer for instrument evaluation and calibration dosimetry and animal bioeffects studies; publish NBS reports on instrument design (75–127, 140).	.9	85,000	119,000
1975—Monitoring (UV) Monitor UV meter contract (KA), evaluation of black light sources, initiate IA with NBS for calibration of standards, publish NBS report of IA (75–131).	.9	5,700	33,450

See footnotes at end of table.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH—Continued

Fiscal year—Category and brief description	Man-years	Extramural funds	Total funds
NONIONIZING RADIATION PROJECTS—Continued			
1975—Monitoring (IR) Purchase equipment to measure IR sources.	.8	0	35,400
1976—Health effects (UV) Monitor UV ocular effects contract; determination of feasibility of identifying UV-induced skin cancer.	.6	0	16,250
1976—Monitoring (RF) Surveys of industrial RF sources (data will provide input for RF bioeffects studies; publish NBS report on development of RF synthesizer (76-160).	1.4	0	42,650
1976—Monitoring (optical) Surveys of optical radiation from welding arcs; contract with American Welding Society provides input on radiation and other hazards from welding for criteria document development.	1.1	25,000	59,000
1976—Health effects (RF) Monitor IA with USAF School of Aerospace Medicine; develop contract with Georgia Tech to determine dielectric properties of human and animal tissue to be used for dosimetry in bio-effects studies.	.7	45,000	63,475
1976—State/Federal liaison (laser) Monitor IA with Army for laser compendium; publish compendium (76-183).	.5	5,000	35,350
1976—Other (literature review) (all NIR)[1] Review of literature on radiation induced cancer, and prepare state-of-art report under contract to Franklin Institute Research Laboratories.	.1	34,500	36,800
1976—State/Federal liaison (microwave) Calibration of OSHA microwave instruments.	.8	0	15,000
1976—Other (training) (all types) 2 presentations of nonionizing radiation safety course.	.1	0	10,000
1977—Health effects (RF) Initiate IA with NBS for RF dosimetry system; plan and initiate RF teratology study; work with Navy on pancreatic cancer study; publish 3 reports from USAF School of Aerospace Medicine (77-146).	2.0	91,000	163,450
1977—Other (literature review) (all NIR) Monitor contract with Franklin Institute.	.3	0	14,175
1977—Health effects (IR, UV) Monitor welding contract; award contract to determine threshold levels for IR ocular effects; monitor UV ocular effects contract; survey of VDT's[2] in regard to alleged radiation-induced cataracts; publish 1st part of UV ocular effects study (77-130).	3.5	52,000	154,000
1977—State/Federal liaison (RF/microwave) Development of RF calibration system to calibrate OSHA RF instruments; calibration of OSHA microwave instruments.	.9	0	20,000
1977—Other (training) (all types) 1 presentation of nonionizing radiation safety course.	.1	0	5,000
1978—Health effects (RF) Continue RF teratology study.	4.0	91,000	268,000
1978—Monitorig (optical) Monitor IR and welding contracts.	2.0	0	92,000
1978—State/Federal liaison (RF/microwave) Development of RF calibration system to calibrate OSHA instruments; calibration of OSHA microwave instruments.	.9	0	15,000
IONIZING RADIATION PROJECTS[3]			
1969—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	21.3	146,000	537,700
1970—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	21.5	137,000	509,000
1971—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	9.7	122,000	568,000
1971—State/Federal liaison (X-ray) Development of X-ray calibration system to calibrate OSHA survey instruments.	.1	0	1,000
1972—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	4.2	62,000	220,000
1972—Monitoring (X-rays) Survey of industrial X-ray facilities in Ohio with FDA/BRH.	.3	0	50,000
1972—State/Federal liaison (X-ray) Development of X-ray calibration system to calibrate OSHA survey instruments.	.1	0	1,000
1973—State/Federal liaison (X-ray) Development of X-ray calibration system to calibrate OSHA survey instruments.	.1	0	15,000

Footnotes at end of table.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH—Continued

Fiscal year—Category and brief description	Man-years	Extramural funds	Total funds
IONIZING RADIATION PROJECTS—Continued			
1973—State/Federal liaison (all types) Review of current OSHA standards; program planning.	1.1	0	20,350
1973—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	4.1	0	117,000
1973—State/Federal liaison (all types) Development of ionizing radiation safety course for OSHA industrial hygienists; 2 presentations of course.	1.0	0	15,000
1974—Monitoring (X-rays) Set-up airport baggage X-ray study with FAA; identify other areas of concern.	.6	0	13,000
1974—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	3.5	0	78,000
1974—Other (training) (all types) Presentation of ionizing radiation safety course.	.3	0	4,000
1974—State/Federal liaison (X-ray) Calibration of OSHA survey instruments.	.1	0	2,000
1975—Monitoring (all types) Initiate contract with Teknekron to study occupational exposure to ionizing radiation sources; surveyed State records for employer violations, accidents, employee doses.	.4	70,000	84,600
1975—Other (training) (all types) Development of package training course on ionizing radiation safety; presentation of 2 courses.	.5	65,000	75,000
1975—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	3.0	0	52,000
1975—State/Federal liaison (X-ray) Calibration of OSHA survey instruments.	.1	0	5,000
1976—Monitoring (all types) Complete airport baggage X-ray study.	.4	0	13,050
1976—Other (literature review) (all types) Summary report of radiation-induced cancer under contract to Franklin Institute.	.1	11,500	13,500
1976—Other (training) (all types) 2 presentations of ionizing radiation safety course.	.1	0	10,000
1976—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	1.2	0	24,000
1976—State/Federal liaison (X-ray) Calibration of OSHA survey instruments.	.2	0	5,000
1977—State/Federal liaison (X-ray) Calibration of OSHA survey instruments.	.2	0	5,000
1977—Monitoring (all types) Complete Teknekron study; recommendations are being evaluated; sent to ANSI N43 subcommittee of industrial radiography; publish Teknekron report and airport baggage study (77-105, 142).	1.0	0	23,500
1977—Other (literature review) (all types) Monitor contract with Franklin Institute report due in fiscal year 1978; publish report.	.1	0	4,725
1977—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	2.0	0	52,000
1977—Other (training) (all types) 1 presentation of ionizing radiation short course.	.1	0	5,000
1978—Collection and/or analysis of health data (uranium) Industry-wide study of uranium miners and millers to determine hazards from exposure to radon daughter products.	2.1	0	52,000
1978—State/Federal liaison (X-ray) Calibration of OSHA survey instruments.	.2	0	2,000
Radiation program total:			
Nonionizing	37.9	846,000	1,850,000
Ionizing	79.7	602,000	2,559,000

NIR—Nonionizing radiation.

[2] VDT—Video display tenical.

[3] In addition to the projects listed, contracts existed with the States of Utah (fiscal year 1968–76), New Mexico (fiscal year 1969–73), and Wyoming (fiscal year 1970–71) for: analysis of epidemiological data on uranium miners; development of an experimental uranium mine; monitoring of uranium mines for radon daughter products physical examinations (including spectrum cytology) of uranium miners; and a study of lead to tin excretion in urine of uranium miners. Contracts also existed (fiscal year 1973–74) with Battelle Northwest for calculations on actual radiation dosage to lungs of uranium miners, and evaluation of methods for setting standards for radon daughter products. Under Public Law-480 authority, contracts existed over the period (fiscal year 1963–74) in Yugoslavia for a uranium miner epidemiological study, and animal and human studies on lead to excretion in the urine following exposure to uranium mine environments.

COMMENT BY ROBERT DUDNICK, ASSOCIATE DIRECTOR OF RESEARCH AND INFORMATION, THE NEWSPAPER GUILD, AFL–CIO, WASHINGTON, D.C.

On June 28, 1977, Dr. Elliott Harris testified to the Committee on behalf of the National Institute for Occupational Safety and Health's Division of Biomedical and Behavioral Science, of which he is the director.

A portion of Dr. Harris' testimony is incomplete and could, if not commented upon, lead those interested in radiation and occupational health to possibly erroneous conclusions.

It is perfectly true, as Dr. Harris has testified, that at our request NIOSH conducted a survey "to measure the radiation emissions from the cathode ray tube (CRT) of video display terminals (VDT) used in a newspaper composition room (sic) where two young employees developed bilateral cataracts."

He adds that levels of optical and RF radiation measured "were several orders of magnitude below existing occupational exposure guidelines."

What Dr. Harris does not say is that The Newspaper Guild did not and does not accept the survey results which his testimony presents as unchallenged. Consultants to the Guild's international office and to its New York Local 3 have grave reservations about the results, methodology and instrumentation.

These reservations were so strongly expressed that Local 3 brought the matter to arbitration. The arbitrator has ordered that a new, non-NIOSH test be conducted at the subject newspaper, the New York Times. The test is pending.

The Newspaper Guild and its Local 3 do not accept the NIOSH findings at the New York Times because there seems to us to be a reasonable doubt as to their accuracy. We do not dismiss the NIOSH report out of hand. We simply believe that we must adopt the most conservative, worst-case position in order to represent the interests of our members.

It is our view, therefore, that the NIOSH survey and the analysis of it as presented in the exhibit attached to this comment indicate that much more research is required before the subject can be laid to rest in the manner in which Dr. Harris attempted to dispose of it.

NIOSH had submitted an interim and final report to The Newspaper Guild and Local 3. In the exhibit that follows this statement, reference is made to both reports. Reference also is made to Dr. Milton Zaret, who commented on the NIOSH reports as consultant to Local 3. The material in the exhibit was developed and written by Dr. Victor Alexander, a physician and industrial hygienist assigned to the AFL–CIO Industrial Union Department. Dr. Alexander has acted as consultant to the Guild's international office in this matter. He submitted these findings to The Newspaper Guild on June 6, 1977.

ANALYSIS OF THE NIOSH NEW YORK TIMES VDT/CRT SURVEY

(By Victor Alexander, M.D.)

The final report from NIOSH on the New York Times Visual Display Terminal/Cathode Ray Tube (VDT/CRT) Survey is significantly modified from its initial version. The content is improved, but a number of defects remain. Pertinent comments will be offered below following the format of the Final Report. A summary will include information on VDT/CRT radiation hazards developed during the analysis of the report in conversations with scientists at Harvard School of Public Health, FDA Laboratory, Winchester, Mass., Bureau of Radiological Health, Rockville, Md., and the Hewlett-Packard Instrument Company.

The first significant change in the report involves the frequency bands in the electromagnetic (EM) spectrum to be surveyed. In the final report for theoretical reasons NIOSH claims the VDT/CRT equipment can't generate emissions with frequencies above 250 Megahertz (MHz). Each of the scientists contacted agreed with his basic supposition, in disagreement with Dr. Zaret's contention (letter of May 3, page 1). However, no one specifically had knowledge of actual measurements made under circumstances of mechanical malfunction. The point is of practical importance because the frequency range of microwaves is 30 MHz-300 Gigahertz (GHz). Furthermore, health effects on the eye have been found only from 915 MHz–10 GHz in the microwave region. Therefore if the machines are not capable of generating emissions above 250 MHz, the source of the cataracts must be sought in another portion of the EM spectrum.

The interim version of the NIOSH report claims to have measured microwave exposure (compare Interim Report, Page 2 with Final Report, Page 6). In fact, the NIOSH survey equipment will operate only from 10 MHz–500 MHz (HP 5303B Frequency Counter, EDM–2 electric field density meter, Narda 8607 magnetic field detector) missing not only the great majority of the microwave band, but *all* of the range in which health effects have been reported. NIOSH's own manual (Industrial Environment-Evaluation and Control 1973, Page 373) recommends a survey instrument responsive to wavelengths from 20 Kilohertz (KHz) to 12.4 GHz.

On theoretical grounds it seems unlikely the equipment would generate microwave emissions, but no reference to field studies measuring levels has been obtained, so perhaps this is an open question. In any event, no acceptable evaluation of microwave emissions has been made by this survey.

The survey instruments chosen for the ultraviolet (UV), visible, infrared (IR), and radiofrequency (RF) emissions seem generally appropriate to the task. Hewlett-Packard did report that the H–P5303B Frequency Counter is only moderately sensitive, and would not be the instrument of choice, suggesting that a spectrum analyzer would be a better selection.

There is no documentation for the choice of 2–3 centimeters (cm) as the distance from the VDT for measurements to be taken. No estimated shape or character of the radiation field, or near/far field profile is offered. In many studies such preliminary calculations are made to better define the best sampling distances.

During the survey on the Telco VDT there was interference from an unidentified source preventing use of the most sensitive scale (Final Report, Page 7). Yet in Table I (Final Report, Page 8) NIOSH reports results using precisely that most sensitive scale. Therefore one cannot rely on the accuracy of the reported integrated UV irradiance of 2.0 x 10–9 Watts cm^2, which in fact is already the highest value for the three VDTs measured, without considering the possible underestimation error due to the electrical interference.

The spectroradiometer was used to survey wavelengths of 350–1150 Nanometers (nm) for coverage of the visible and near infrared spectra. The usual reported extent of the near IR band is 700–1400 nm (NIOSH Industrial Environment, Page 366). This discrepancy is not consistent with the implied goal of a complete evaluation of potential radiation hazards (Final Report, Page 1), requested by the New York Times management.[1]

A frequency between 1 and 2 MHz was detected on the Telco VDT, but no quantitation of the energy levels could be obtained because the survey equipment does not operate below 10 MHz. This is pertinent since it is in precisely the range of 1–30 MHz that health effects are least well defined, and the smallest amount of research and data are available.

The description of the survey instruments carefully states the spectroradiometer measures UV wavelengths from 200–400 nm. Yet no values are reported for wavelengths below 300 nm. In effect, the survey was conducted for UV wavelengths from 300–400 nm. The peak of relative effectiveness for UV induced photokeratitis is 280 nm, that of skin carcinogenisis in man is approximately 295 nm (NIOSH Industrial Environment, Page 360). No effects of this kind are postulated in the present situation; the survey is again incomplete, ignoring areas of well-demonstrated biological effect.

An emission at 27 MHz from the Harris VDT was detected. NIOSH notes that at 12 cm the signal was not detectable (Final Report, Page 11). The strength at 2 cm is not recorded. Yet in the summary Table 6 (Final Report, Page 17) the maximum measured level is given as not detectable. The Instrumentation and Procedure section (Final Report, Page 6) clearly states that RF measurements were to be made at 2–3 cm, without any indication of modifying conditions. It is arguable at what particular distance measurements ought to be performed. But to offer the conclusions in Table 6 is playing fast and loose with the survey conditions the report writers set for themselves. A similar criticism applies for electrical field strength measurements reported in Table 2 (Final Report, Page 10).

Certain comparative measurements on other VDT's in the building were made; but only for luminance, and the RF band. The inciting cause for the survey was the report of cataracts in two VDT workers. The probable etiology of occupational cataracts, if the employee's cataracts are job related, would lead to measurement of exactly those EM bands not measured for comparison—that is, UV, IR, and microwave as the more potent cataractogenic agents.

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[1] In fact. the evaluation was requested by The Newspaper Guild and Local 3, Newspaper Guild of New York, with the assistance of the AFL–CIO Industrial Union Department.

Magnetic field measurements on the seventh floor yielded a value of 1 milliwatt/cm² (Final Report, Page 13). This result was dismissed as caused by a nearby radio station because similar readings were obtained in an adjoining room and near window ledges. Each of four scientists contacted was concerned at this relatively high value. The speculation in the report for the source of emission is not supported by any evidence whatever. Further measurements in the Times building, on other floors, and a serious attempt to trace the origin of the emission are clearly and unmistakeably called for. The report is silent. To then estimate the value of magnetic field levels as zero is not justifiable.

X-ray measurements at the Times were not performed during this survey because results from a study at the Baltimore Sun are available (Final Report, Pages 2 and 3). The introduction to the Final Report (Page 2) states that the survey was done on 125 VDTs in Baltimore. The results reported in the main text are that 20% of the VDTs were measured on all six sides. It is not clear whether 20% of the 125 VDTs were measured, each on all sides, or all 125 were measured, 20% on all sides. Either way, fewer machines than expected were measured reducing the value of the results. Furthermore, only 75 machines in Baltimore were Harris 1500A models similar to those at the Times; there were no Telco or Incoterm models.

The report draws conclusions about radiation levels solely from ranges and maximum values for VDT emissions and background, without reporting any mean, average or distribution. No conclusions can be drawn from such incomplete data.

A second significant change in the report drafts is the use of a different reference standard for X-ray exposure. The interim report claimed the Sun results were less than the FDA standard for television receivers of .5 milliroentgens (mr) per hour. (Interim Report, Page 1). In fact the results in the final version (Final Report, Page 17) may very well conceal exposures of .5 mr/hr if the results were completely reported. (Maximum radiation measured .85 mr/hr, minimum background .16 mr/hr). However, a new standard of 2.5 mr/hr from OSHA is used (Final Report, Page 17). Where there are conflicting standards, good practice requires the use of the more stringent requirement. The data presented do not substantiate the report's conclusions about lack of possible X-ray exposure from VDTs.

The Harris VDT has a cathode ray tube which operates at a potential of 23–33 Kilowatts. The Bureau of Radiological Health scientists contacted reported that any such tube operating at greater than 20 KV is a potential X-ray source. They indicated their desire to make an independent survey of the VDT/CRT at the Times after a request by the Newspaper Guild in this matter. They expressed particular concern since these VDT/CRT sources are not legally classified as television receivers; and the BRH therefore lack enforcement powers, a situation they are actively trying to change.

There seems to be no significant disagreement that the cataracts referred to in the medical section are similar to and consistent with radiation induced injury. There is also no evidence for congenital, diabetic or steroid non-occupational causes. The NIOSH report claims to have eliminated the VDT as a possible source of radiation in the genesis of the cataracts. We cannot subscribe to that claim. The significant omissions, misstatements, and unwarranted conclusions of the report are reviewed above. The report is not only incomplete, but those areas covered are not always well done. The evidence offered does not decide the issues.

It appears that based on theoretical design criteria, microwaves are an unlikely VDT emission hazard. The UV band was not completely surveyed, nor was the IR range. Not enough is known about health effects in the RF spectrum and several frequencies in this range at 1 MHz, 20 MHz, and 27 MHz were found. A more persistent inquiry into the magnetic field reading on the seventh floor is indicated.

U.S. Department of Labor,
Washington, D.C., June 24, 1977.

Hon. Wendell H. Ford,
Chairman, Consumer Subcommittee, U.S. Senate,
Washington, D.C.

Dear Mr. Chairman: This is in response to your joint letter with Senator Adlai T. Stevenson on May 19, 1977, for information concerning the radiation control activities within the Occupational Safety and Health Administration (OSHA).

Response to the specific questions are enclosed as attachment A. Comments concerning the matrix like charts are enclosed as attachment B.

If we can assist you further please feel free to contact me.

Sincerely,

EULA BINGHAM,
Assistant Secretary,
Occupational Safety and Health.

Enclosures.

ATTACHMENT A

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e. inception of new agencies, transfer of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. *a.* The major legislation for us in this period is our enabling legislation, the Occupational Safety and Health Act of 1970 (OSH Act). Pursuant to it OSHA has promulgated standards applicable to general industry concerning both ionizing and non-ionizing radiation. For ionizing radiation, these standards (enclosure 1) are basically those adopted by incorporation from regulations promulgated under the Walsh-Healy Public Service Contracts Act which in turn were derived from AEC regulations. Prior to OSHA coverage, the regulations extended to government contractors and to all employers in AEC-Agreement states. Under OSHA the coverage had been extended in 1971 to cover all employers nationwide.

The regulations for non-ionizing radiation, also first published in 1971, were derived from two voluntary national consensus standards of the American National Standards Institute (ANSI) concerning microwave radiation. These regulations (enclosure 2) established Federal regulation cover microwave exposure and were applicable to all employers.

b. OSHA safety and health regulations (enclosure 3) for the construction industry are issued under the authority of the Contracts Work Hours and Safety Standards Act of 1969. For ionizing radiation these standards reference 10 CFR 20 and are therefore essentially the same as the general industry standards. The limit for microwaves is also the same as for general industry. The construction standards include provisions to limit exposures to laser radiation.

c. The President's Reorganization Plan No. 3 of 1970 creating the Environmental Protection Agency (EPA) transferred to EPA some of the former responsibilities of the Federal Radiation Council. The EPA is charged to review and issue guidance to all Federal agencies concerning the regulation of exposure to ionizing radiation. Federal agencies then must stay within these guidelines when issuing regulations. OSHA's present regulations are well within the current guidelines; therefore this change of authority has had no effect on our activity to date.

Question 2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field? Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of State and Federal agencies?

Answer. *a.* Generally no special coordination with state agencies is required or necessary in implementing our program. However, if a state becomes a State Plan State under section 18 of the OSH Act, then interaction is necessary to establish that the state plan is adequate and to monitor the execution of the state program with respect to the requirement that state standards and the enforcement of them is "at least as effective in providing safe and healthful employment" . . . . as the Federal standards. Without a state plan, state regulations are preempted by Federal OSHA regulations.

b. Confusion over jurisdiction has resulted in the case where on OSHA State Plan state is also an NRC-Agreement state. As a result, OSHA has held meetings with representatives of all states concerning the jurisdictional issues and the contents of ionizing radiation standards. OSHA has also maintained contact with the model regulation drafting activities by the states and with the Bureau of Radiological Health in FDA.

c. The NRC jurisdiction covers three classes of material known as "special nuclear material", "byproduct material" and "source material". OSHA jurisdiction covers such items as X-ray producing machinery, naturally occurring radioisotopes and radioisotopes produced with devices such as cyclotrons.

Question 3. Would you please provide the committee with your thoughts on how the present regulation of radiation programs could be improved? Are there any present deficiences of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. *a.* With the exception of the jurisdictional issue discussed above, OSHA believes the present allocation of responsibilities for radiation regulation is generally satisfactory. However, emphasis should continue to be placed on interagency coordination of radiation programs to promote consistency among the regulations and to avoid unwarranted overlap of activities.

b. OSHA has announced its intention to simplify and update our existing standards, many of which had been adopted from voluntary consensus standards or from the regulations of other Federal Agencies. The OSHA radiation standards are among those standards and would be considered for improvement under this project.

c. OSHA was recently reorganized, creating an Office of Physical Agents Standards under the Directorate of Health Standards Programs. The Office's responsibility will be for development of all OSHA physical agent standards, including radiation standards. We are in the process of staffing that office to provide a more effective program for development of these standards. In addition, OSHA is increasing both the numbers and quality of our health enforcement staff, which will improve our effectiveness in ensuring compliance with our radiation standards.

Question 4. What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal Radiation Agency?

Answer. As you are aware, the Administration is considering reorganizing the Executive Branch Departments to better effectuate the authorities of these agencies. Until completion of this review, we do not believe it is appropriate to comment on possible legislative proposals for reorganization.

NOTES TO MATRIX INFORMATION

1. OSHA does not perform or sponsor original research projects. The National Institute for Occupational Safety and Health (NIOSH) in DHEW generally does this for the field of occupational safety and health.

2. Ecological and environmental effects are to be considered in the preparation of environmental impact statements for individual standards projects. No environmental impact statements have been prepared for ionizing or non-ionizing radiation standards projects to date, but would be prepared before new standards are issued.

3. This is outside the jurisdiction of OSHA.

4. Criteria development is performed by NIOSH and submitted to OSHA in "Criteria Documents" which are used as part of the basis for formulating standards. Data presented are for man-years devoted to standards development, including estimates for supervision and clerical support.

5. Numbers include staff of State Programs national office, regional office staff, and state plan monitors at area offices, prorated to the proportion of inspections devoted to radiation of each type expressed as man-weeks.

6. Licensing and certification are not performed by OSHA. Numbers of inspections performed concerning radiation are shown. Data prior to FY 74 would be very difficult to compile due to differences in recordkeeping procedures at that time.

7. Numbers of measurements taken to support the inspections shown in previous column.

8. Collection of health data in the form of literature review and consultation with experts and the analysis of the resulting information is performed as a part of our standards development actiivty which is reflected in column 5 "Criteria and or standards development."

9. "L"=lasers; "uv"=ultraviolet; "mw"=microwaves.

10. No extramural funds are involved. Data on these tables reflect only federal activity and do not include activity by state personnel operating under State Plans. Note that OSHA was not formed until 1971.

NON-IONIZING RADIATION* §

*(lasers and microwaves)

Year	Studies to determine human health effects	Ecological efforts Animals Plant	Agricultrual efforts Plant/Animal	Criteria and/or Standards Development	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of enviromental data	Other biological or physical effects studies	Other Studies (Explain)
1970	none see note 1	none see note 2	none see note 3	see note 4	see note 5	see notes 6, 9	see note 7	none see note 3	see note 8	none see note 2	none note 3	none
1971	"	"	"	1/2		--	--	"	"	"	"	"
1972	"	"	"	1/2		--	--	"	"	"	"	"
1973	"	"	"	1/2		--	--	"	"	"	"	"
1974	"	"	"	1/2	.45	4-MW	31-MW	"	"	"	"	"
1975	"	"	"	1	1.6	1-L 1-UV 14-MW	2-L 2-UV 159-MW	"	"	"	"	"
1976	"	"	"	1	2.5	4-L 25-MW	31-L 467-MW	"	"	"	"	"
1977	"	"	"	1/2	Oct-May 1.2	Oct-May 9-MW	Oct-May 9-MW	"	"	"	"	"
Est. 1978	"	"	"	2	--	--	--	"	"	"	"	"

IONIZING RADIATION* §

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultrual efforts Plant/Animal	Criteria and/or Standards Development	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of enviromental data	Other biological or physical effects studies	Other Studies (Explain)
1970	none see note 1	none see note 2	none see note 3	see note 4	see note 5	see note 6	see note 7	none see note 3	see note 8	none see note 2	none note 3	none
1971	"	"	"	1/2		--	--	"	"	"	"	"
1972	"	"	"	1/2		--	--	"	"	"	"	"
1973	"	"	"	1		--	--	"	"	"	"	"
1974	"	"	"	1	4.6	43	460	"	"	"	"	"
1975	"	"	"	1	2.3	24	312	"	"	"	"	"
1976	"	"	"	1/2	2.4	28	395	"	"	"	"	"
1977	"	"	"	1/2	Oct-May 1.7	Oct-May 13	Oct-May 67	"	"	"	"	"
Est. 1978	"	"	"	2				"	"	"	"	"

(c) Ground returns and machine grounding.

(1) A ground return cable shall have a safe current carrying capacity equal to or exceeding the specified maximum output capacity of the arc welding or cutting unit which it services. When a single ground return cable services more than one unit, its safe current carrying capacity shall equal or exceed the total specified maximum output capacities of all the units which it services.

(2) Structures or pipe lines, except pipe lines containing gases or flammable liquids or conduits containing electrical circuits, may be used as part of the ground return circuit, provided that the pipe or structure has a current carrying capacity equal to that required by subparagraph (1) of this paragraph.

(3) When a structure or pipe line is employed as a ground return circuit, it shall be determined that the required electrical contact exists at all points. The generation of an arc, sparks or heat at any point shall cause rejection of the structure as a ground circuit.

(4) When a structure or pipe line is continuously employed as a ground return circuit, all joints shall be bonded, and periodic inspections shall be conducted to ensure that no condition of electrolysis or fire hazard exists by virtue of such use.

(5) The frames of all arc welding and cutting machines shall be grounded either through a third wire in the cable containing the circuit conductor or through a separate wire which is grounded at the source of the current. Grounding circuits, other than by means of the vessel's structure, shall be checked to ensure that the circuit between the ground and the grounded power conductor has resistance low enough to permit sufficient current to flow to cause the fuse or circuit breaker to interrupt the current.

(6) All ground connections shall be inspected to ensure that they are mechanically strong and electrically adequate for the required current.

(d) Operating instructions.

Employers shall instruct employees in the safe means of arc welding and cutting as follows:

(1) When electrode holders are to be left unattended, the electrodes shall be removed and the holders shall be so placed or protected that they cannot make electrical contact with employees or conducting objects.

(2) Hot electrode holders shall not be dipped in water, since to do so may expose the arc welder or cutter to electric shock.

(3) When the arc welder or cutter has occasion to leave his work or to stop work for any appreciable length of time, or when the arc welding or cutting machine is to be moved, the power supply switch to the equipment shall be opened.

(4) Any faulty or defective equipment shall be reported to the supervisor.

(e) Shielding.

Whenever practicable, all arc welding and cutting operations shall be shielded by noncombustible or flame-proof screens which will protect employees and other persons working in the vicinity from the direct rays of the arc.

1915.37—USES OF FISSIONABLE MATERIAL IN SHIP REPAIR

(a) In ship repair and related activities involving the use of and exposure to sources of ionizing radiation not only on conventionally powered but also on nuclear powered vessels, the applicable provisions of the Atomic Energy Commission's Standards for Protection Against Radiation (10 CFR Part 20), relating to protection against occupational radiation exposure, shall apply.

(b) Any activity which involves the use of radioactive material, whether or not under

TABLE D-2—PERMISSIBLE NOISE EXPOSURES

Duration per day, hours:	*Sound level dBA slow response*
8	90
6	92
4	95
3	97
2	100
1½	102
1	105
½	110
¼ or less	115

(2)

(i) When the daily noise exposure is composed of two or more periods of noise exposure of different levels, their combined effect should be considered, rather than the individual effect of each. Exposure to different levels for various periods of time shall be computed according to the formula set forth in subdivision (ii) of this subparagraph.

(ii)

$$F_6 = \frac{T_1}{L_1} + \frac{T_2}{L_2} + \cdots + \frac{T_n}{L_n}$$

where:

F_6 = The equivalent noise exposure factor.

T = The period of noise exposure at any essentially constant level.

L = The duration of the permissible noise exposure at the constant level (from Table D-2).

If the value of F_6 exceeds unity (1) the exposure exceeds permissible levels.

(iii) A sample computation showing an application of the formula in subdivision (ii) of this paragraph is as follows. An employee is exposed at these levels for these periods:

110 dba ¼ hour.
100 dba ½ hour.
90 dba 1½ hour.

$$F_6 = \frac{1/4}{1/2} + \frac{1/2}{2} + \frac{1\tfrac{1}{2}}{8}$$

$$F_6 = 0.500 + 0.25 + 0.188$$
$$F_6 = 0.938$$

Since the value of F_6 does not exceed unity, the exposure is within permissible limits.

(e) Exposure to impulsive or impact noise should not exceed 140 dB peak sound pressure level.

1926.53—IONIZING RADIATION

(a) In construction and related activities involving the use of sources of ionizing radiation, the pertinent provisions of the Atomic Energy Commission's Standards for Protection Against Radiation (10 CFR Part 20), relating to protection against occupational radiation exposure, shall apply.

(b) Any activity which involves the use of radioactive materials or X-rays, whether or not under license from the Atomic Energy Commission, shall be performed by competent persons specially trained in the proper and safe operation of such equipment. In the case of materials used under Commission license, only persons actually licensed, or competent persons under direction and supervision of the licensee, shall perform such work.

1926.54—NONIONIZING RADIATION

(a) Only qualified and trained employees shall be assigned to install, adjust, and operate laser equipment.

(b) Proof of qualification of the laser equipment operator shall be available and in possession of the operator at all times.

(c) Employees, when working in areas in which a potential exposure to direct or reflected laser light greater than 0.005 watts (5 milliwatts) exists, shall be provided with antilaser eye protection devices as specified in Subpart E of this part.

(d) Areas in which lasers are used shall be posted with standard laser warning placards.

(e) Beam shutters or caps shall be utilized, or the laser turned off, when laser transmission is not actually required. When the laser is left unattended for a substantial period of time, such as during lunch hour, overnight, or at change of shifts, the laser shall be turned off.

(f) Only mechanical or electronic means shall be used as a detector for guiding the internal alignment of the laser.

(g) The laser beam shall not be directed at employees.

(h) When it is raining or snowing, or when there is dust or fog in the air, the operation of laser systems shall be prohibited where practicable; in any event, employees shall be kept out of range of the area of source and target during such weather conditions.

(i) Laser equipment shall bear a label to indicate maximum output.

(j) Employees shall not be exposed to light intensities above:

(1) Direct staring: 1 micro-watt per square centimeter;

(2) Incidental observing: 1 milliwatt per square centimeter;

(3) Diffused reflected light: 2½ watts per square centimeter.

(k) Laser unit in operation should be set up above the heads of the employees, when possible.

(l) Employees shall not be exposed to microwave power densities in excess of 10 milliwatts per square centimeter.

1926.55—GASES, VAPORS, FUMES, DUSTS, AND MISTS

(a) Exposure of employees to inhalation, ingestion, skin absorption, or contact with any material or substance at a concentration above those specified in the "Threshold Limit Values of Airborne Contaminants for 1970" of the American Conference of Governmental Industrial Hygienists, shall be avoided.

(b) To achieve compliance with paragraph (a) of this section, administrative or engineering controls must first be implemented whenever feasible. When such controls are not feasible to achieve full compliance, protective equipment or other protective measures shall be used to keep the exposure of employees to air contaminants within the limits prescribed in this section. Any equipment and technical measures used for this purpose must first be approved for each particular use by a competent industrial hygienist or other shall be protected by means of rubber and friction tapes or other equivalent insulation.

(c) Ground returns and machine grounding.

(1) A ground return cable shall have a safe current carrying capacity equal to or exceeding the specified maximum output capacity of the arc welding or cutting unit which it services. When a single ground return cable services more than one unit, its safe current carrying capacity shall equal or exceed the total specified maximum output capacities of all the units which it services.

(2) Structures or pipe lines, except pipe lines containing gases or flammable liquids or conduits containing electrical circuits, may be used as part of the ground return circuit, provided that the pipe or structure has a current carrying capacity equal to that required by subparagraph (1) of this paragraph.

(3) When a structure of pipe line is employed as a ground return circuit, it shall be determined that the required electrical contact exists at all joints. The generation of an arc, sparks or heat at any point shall cause rejection of the structure as a ground circuit.

(4) When a structure or pipe line is continuously employed as a ground return circuit, all joints shall be bonded, and periodic inspections shall be conducted to ensure that no condition of electrolysis or fire hazard exists by virtue of such use.

(5) The frames of all arc welding and cutting machines shall be grounded either through a third wire in the cable containing the circuit conductor or through a separate wire which is grounded at the source of the current. Grounding circuits, other than by means of the vessel's structure, shall be checked to ensure that the circuit between the ground and the grounded power conductor has resistance low enough to permit sufficient current to flow to cause the fuse or circuit breaker to interrupt the current.

(6) All ground connections shall be inspected to ensure that they are mechanically strong and electrically adequate for the required current.

(d) Operating instructions.

Employers shall instruct employees in the safe means of arc welding and cutting as follows:

(1) When electrode holders are to be left unattended, the electrodes shall be removed and the holders shall be so placed or protected that they cannot make electrical contact with employees or conducting objects.

(2) Hot electrode holders shall not be dipped in water, since to do so may expose the arc welder or cutter to electric shock.

(3) When the arc welder or cutter has occasion to leave his work or to stop work for any appreciable length of time, or when the arc welding or cutting machine is to be moved, the power supply switch to the equipment shall be opened.

(4) Any faulty or defective equipment shall be reported to the supervisor.

(e) Shielding.

Whenever practicable, all arc welding and cutting operations shall be shielded by noncombustible or flame-proof screens which will protect employees and other persons working in the vicinity from the direct rays of the arc.

1916.37—USES OF FISSIONABLE MATERIAL IN SHIPBUILDING

(a) In shipbuilding and related activities involving the use of an exposure to sources of ionizing radiation not only on conventionally powered but also on nuclear powered vessels, the applicable provisions of the Atomic Energy Commission's Standards for Protection Against Radiation (10 CFR Part 20), relating to protection against occupational radiation exposure, shall apply.

(b) Any activity which involves the use of radioactive material, whether or not under license from the Atomic Energy Commission, shall be performed by competent persons specially trained in the proper and safe operation of such equipment. In the case of materials used under Commission license, only persons actually licensed, or competent persons under direction and supervision of the licensee, shall perform such work.

(2) If the variations in noise level involve maxima at intervals of 1 second or less, it is to be considered continuous.

(3) In all cases where the sound levels exceed the values shown herein, a continuing, effective hearing conservation program shall be administered.

1910.96—IONIZING RADIATION

(a) Definitions applicable to this section.

(1) "Radiation" includes alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but such term does not include sound or radio waves, or visible light, or infrared or ultraviolet light.

(2) "Radioactive material" means any material which emits, by spontaneous nuclear disintegration, corpuscular or electromagnetic emanations.

(3) "Restricted area" means any area access to which is controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

(4) "Unrestricted area" means any area access to which is not controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

(5) "Dose" means the quantity of ionizing radiation absorbed, per unit of mass, by the body or by any portion of the body. When the provisions in this section specify a dose during a period of time, the dose is the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time. Several different units of dose are in current use. Definitions of units used in this section are set forth in subparagraphs (6) and (7) of this paragraph.

(6) "Rad" means a measure of the dose of any ionizing radiation to body tissues in terms of the energy absorbed per unit of mass of the tissue. One rad is the dose corresponding to the absorption of 100 ergs per gram of tissue (1 millirad (mrad) = 0.001 rad).

(7) "Rem" means a measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of 1 roentgen (r) of X-rays (1 millirem (mrem) =0.001 rem). The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions for irradiation. Each of the following is considered to be equivalent to a dose of 1 rem:

(i) A dose of 1 (r) due to X- or gamma radiation;

(ii) A dose of 1 rad due to X-, gamma, or beta radiation;

(iii) A dose of 0.1 rad due to neutrons or high energy protons;

(iv) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;

(v) If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, as provided in subdivision (iii) of this subparagraph, 1 rem of neutron radiation may, for purposes of the provisions in this section be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there is sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to 1 rem may be estimated from Table G-17:

TABLE G-17—NEUTRON FLUX DOSE EQUIVALENTS

Neutron energy (million electron volts (Mev))	Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm^2)	Average flux to deliver 100 millirem in 40 hours (neutrons/cm^2 per sec.)
Thermal	970 × 10^6	670
0.0001	720 × 10^6	500
0.005	820 × 10^6	570
0.02	400 × 10^6	280
0.1	120 × 10^6	80
0.5	43 × 10^6	30
1.0	26 × 10^6	18
2.5	29 × 10^6	20
5.0	26 × 10^6	18
7.5	24 × 10^6	17
10	24 × 10^6	17
10 to 30	14 × 10^6	10

(8) For determining exposures to X- or gamma rays up to 3 Mev., the dose limits specified in this section may be assumed to be equivalent to the "air dose." For the purpose of this section "air dose" means that the dose is measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dosage rate.

(b) Exposure of individuals to radiation in restricted areas.

(1) Except as provided in subparagraph (2) of this paragraph, no employer shall possess, use, or transfer sources of ionizing radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from sources in the employer's possession or control a dose in excess of the limits specified in Table G-18:

TABLE G-18

	Rems per calendar quarter
Whole body: Head and trunk; active blood-forming organs; lens of eyes; or gonads	1¼
Hands and forearms; feet and ankles	18¾
Skin of whole body	7½

(2) An employer may permit an individual in a restricted area to receive doses to the whole body greater than those permitted under subparagraph (1) of this paragraph, so long as:

(i) During any calendar quarter the dose to the whole body shall not exceed 3 rems; and

(ii) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N–18) rems, where "N" equals the individual's age in years at his last birthday; and

(iii) The employer maintains adequate past and current exposure records which show that the addition of such a dose will not cause the individual to exceed the amount authorized in this subparagraph. As used in this subparagraph, "dose to the whole body" shall be deemed to include any dose to the whole body, gonad, active bloodforming organs, head and trunk, or lens of the eye.

(3) No employer shall permit any employee who is under 18 years of age to receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in Table G–18.

(4) "Calendar quarter" means any 3-month period determined as follows:

(i) The first period of any year may begin on any date in January: *Provided*, That the second, third, and fourth periods accordingly begin on the same date in April, July, and October, respectively, and that the fourth period extends into January of the succeeding year, if necessary to complete a 3-month quarter. During the first year of use of this method of determination, the first period for that year shall also include any additional days in January preceding the starting date for the first period; or

(ii) The first period in a calendar year of 13 complete, consecutive calendar weeks; the second period in a calendar year of 13 complete consecutive weeks; the third period in a calendar year of 13 complete, consecutive calendar weeks; the fourth period in a calendar year of 13 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling within a complete calendar week of that year, such days shall be included within the last complete calendar week of that year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included within the last complete calendar week of the previous year; or

(iii) The four periods in a calendar year may consist of the first 14 complete, consecutive calendar weeks; the next 12 complete, consecutive calendar weeks, the next 14 complete, consecutive calendar weeks, and the last 12 complete, consecutive calendar weeks. If at the end of a calendar year there are any days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete calendar week of the year. If at the beginning of any calendar year there are days not falling within a complete calendar week of that year, such days shall be included (for purposes of this section) within the last complete week of the previous year.

(5) No employer shall change the method used by him to determine calendar quarters except at the beginning of a calendar year.

(c) Exposure to airborne radioactive material.

(1) No employer shall possess, use or transport radioactive material in such a manner as to cause any employee, within a restricted area, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table 1 of Appendix B to 10 CFR Part 20. The limits given in Table 1 are for exposure to the concentrations specified for 40 hours in any workweek of 7 consecutive days. In any such period where the number of hours of exposure is less than 40, the limits specified in the table may be increased proportionately. In any such period where the number of hours of exposure is greater than 40, the limits specified in the table shall be decreased proportionately.

(2) No employer shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Table II of Appendix B to 10 CFR Part 20. For purposes of this subparagraph, concentrations may be averaged over periods not greater than 1 week.

(3) "Exposed" as used in this paragraph means that the individual is present in an airborne concentration. No allowance shall be made for the use of protective clothing or equipment, or particle size.

(d) Precautionary procedures and personal monitoring.

(1) Every employer shall make such surveys as may be necessary for him to comply with the provisions in this section. "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

(2) Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, to, and shall require the use of such equipment by:

(i) Each employee who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in paragraph (b)(1) of this section; and

(ii) Each employee under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in paragraph (b)(1) of this section; and

(iii) Each employee who enters a high radiation area.

(3) As used in this section:

(i) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.);

(ii) "Radiation area" means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any 1 hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirem; and

(iii) "High radiation area" means any area, accessible to personnel, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirem.

(e) Caution signs, labels, and signals.

(1) General.

(i) Symbols prescribed by this paragraph shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this paragraph is the conventional three-bladed design:

(ii) In addition to the contents of signs and labels prescribed in this paragraph, employers may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation or to radioactive material.

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.

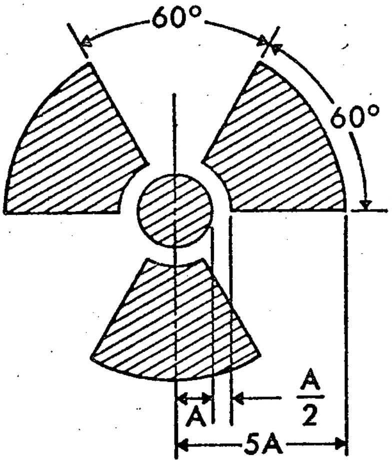


FIGURE G–10

(2) Radiation area. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
RADIATION AREA

(3) High radiation area.

(i) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
HIGH RADIATION AREA

(ii) Each high radiation area shall be

equipped with a control device which shall either cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area or shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering and the employer or a supervisor of the activity are made aware of the entry. In the case of a high radiation area established for a period of 30 days or less, such control device is not required.

(4) Airborne radioactivity area.

(i) As used in the provisions of this section, "airborne radioactivity area" means:

(a) Any room, enclosure, or operating area in which airborne radioactive materials, composed wholly or partly of radioactive material, exist in concentrations in excess of the amounts specified in column 1 of Table 1 of Appendix B to 10 CFR Part 20 or

(b) Any room, enclosure, or operating area in which airborne radioactive materials exist in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in column 1 of Table 1 of Appendix B to 10 CFR Part 20.

(ii) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
AIRBORNE RADIOACTIVITY AREA

(5) Additional requirements.

(i) Each area or room in which radioactive material is used or stored and which contains any radioactive material (other than natural uranium or thorium) in any amount exceeding 10 times the quantity of such material specified in Appendix C to 10 CFR Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
RADIOACTIVE MATERIALS

(ii) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity of such material specified in 10 CFR Part 20 shall be conspicuously posted with a sign or signs bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
RADIOACTIVE MATERIALS

(6) Containers.

(i) Each container in which is transported, stored, or used a quantity of any radioactive material (other than natural uranium or thorium) greater than the quantity of such material specified in Appendix C to 10 CFR Part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
RADIOACTIVE MATERIALS

(ii) Each container in which natural uranium or thorium is transported, stored, or used in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR Part 20 shall bear a durable, clearly visible label bearing the radiation caution symbol described in subparagraph (1) of this paragraph and the words:

CAUTION
RADIOACTIVE MATERIALS

(iii) Notwithstanding the provisions of subdivisions (i) and (ii) of this subparagraph a label shall not be required:

(a) If the concentration of the material in the container does not exceed that specified in column 2 of Table 1 of Appendix B to 10 CFR Part 20, or

(b) For laboratory containers, such as beakers, flasks, and test tubes, used transiently in laboratory procedures, when the user is present.

(iv) Where containers are used for storage, the labels required in this subparagraph shall state also the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantities.

(f) Immediate evacuation warning signal.

(1) Signal characteristics.

(i) The signal shall be a midfrequency complex sound wave amplitude modulated at a subsonic frequency. The complex sound wave in free space shall have a fundamental frequency (f_1) between 450 and 500 hertz (Hz) modulated at a subsonic rate between 4 and 5 hertz.

(ii) The signal generator shall not be less than 75 decibels at every location where an individual may be present whose immediate, rapid, and complete evacuation is essential.

(iii) A sufficient number of signal units shall be installed such that the requirements of subdivision (ii) of this subparagraph are met at every location where an individual may be present whose immediate, rapid, and complete evacuation is essential.

(iv) The signal shall be unique in the plant or facility in which it is installed.

(v) The minimum duration of the signal shall be sufficient to insure that all affected persons hear the signal.

(vi) The signal-generating system shall respond automatically to an initiating event without requiring any human action to sound the signal.

(2) Design objectives.

(i) The signal-generating system shall be designed to incorporate components which enable the system to produce the desired signal each time it is activated within one-half second of activation.

(ii) The signal-generating system shall be provided with an automatically activated secondary power supply which is adequate to simultaneously power all emergency equipment to which it is connected, if operation during power failure is necessary, except in those systems using batteries as the primary source of power.

(iii) All components of the signal-generating system shall be located to provide maximum practicable protection against damage in case of fire, explosion, corrosive atmosphere, or other environmental extremes consistent with adequate system performance.

(iv) The signal-generating system shall be designed with the minimum number of components necessary to make it function as intended, and should utilize components which do not require frequent servicing such as lubrication or cleaning.

(v) Where several activating devices feed activating information to a central signal generator, failure of any activating device shall not render the signal-generator system inoperable to activating information from the remaining devices.

(vi) The signal-generating system shall be designed to enhance the probability that alarm occurs only when immediate evacuation is warranted. The number of false alarms shall not be so great that the signal will come to be disregarded and shall be low enough to minimize personal injuries or excessive property damage that might result from such evacuation.

(3) Testing.

(i) Initial tests, inspections, and checks of the signal-generating system shall be made to verify that the fabrication and installation were made in accordance with design plans and specifications and to develop a thorough knowledge of the performance of the system and all components under normal and hostile conditions.

(ii) Once the system has been placed in service, periodic tests, inspections, and checks shall be made to minimize the possibility of malfunction.

(iii) Following significant alterations or revisions to the system, tests and checks similar to the initial installation tests shall be made.

(iv) Tests shall be designed to minimize hazards while conducting the tests.

(v) Prior to normal operation the signal-generating system shall be checked physically and functionally to assure reliability and to demonstrate accuracy and performance. Specific tests shall include:

(a) All power sources.

(b) Calibration and calibration stability.

(c) Trip levels and stability.

(d) Continuity of function with loss and return of required services such as AC or DC power, air pressure, etc.

(e) All indicators.

(f) Trouble indicator circuits and signals, where used.

(g) Air pressure (if used).

(h) Determine that sound level of the signal is within the limit of subparagraph (1)(ii) of this paragraph at all points that require immediate evacuation.

(vi) In addition to the initial startup and operating tests, periodic scheduled performance tests and status checks must be made to insure that the system is at all times operating within design limits and capable of the required response. Specific periodic tests or checks or both shall include:

(a) Adequacy of signal activation device.

(b) All power sources.

(c) Function of all alarm circuits and trouble indicator circuits including trip levels.

(d) Air pressure (if used).

(e) Function of entire system including operation without power where required.

(f) Complete operational tests including sounding of the signal and determination that sound levels are adequate.

(vii) Periodic tests shall be scheduled on the basis of need, experience, difficulty, and disruption of operations. The entire system should be operationally tested at least quarterly.

(viii) All employees whose work may necessitate their presence in an area covered by the signal shall be made familiar with the actual sound of the signal—preferably as it sounds at their work location. Before placing the system into operation, all employees normally working in the area shall be made acquainted with the signal by actual demonstration at their work locations.

(g) Exceptions from posting requirements.

Notwithstanding the provisions of paragraph (e) of this section:

(1) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 millirem per hour.

(2) Rooms or other areas in onsite medical facilities are not required to be posted with

caution signs because of the presence of patients containing radioactive material, provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in the provisions of this section.

(3) Caution signs are not required to be posted at areas or rooms containing radioactive materials for periods of less than 8 hours: *Provided,* That

(i) The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in the provisions of this section; and

(ii) Such area or room is subject to the employer's control.

(h) Exemptions for radioactive materials packaged for shipment.

Radioactive materials packaged and labeled in accordance with regulations of the Department of Transportation published in 49 CFR Chapter I, are exempt from the labeling and posting requirements of this subpart during shipment, provided that the inside containers are labeled in accordance with the provisions of paragraph (e) of this section.

(i) Instruction of personnel, posting.

(1) Employers regulated by the Atomic Energy Commission shall be governed by 10 CFR Part 20 standards. Employers in a State named in paragraph (p)(3) of this section shall be governed by the requirements of the laws and regulations of that State. All other employers shall be regulated by the following:

(2) All individuals working in or frequenting any portion of a radiation area shall be informed of the occurrence of radioactive materials or of radiation in such portions of the radiation area; shall be instructed in the safety problems associated with exposure to such materials or radiation and in precautions or devices to minimize exposure; shall be instructed in the applicable provisions of this section for the protection of employees from exposure to radiation or radioactive materials; and shall be advised of reports of radiation exposure which employees may request pursuant to the regulations in this section.

(3) Each employer to whom this section applies shall post a current copy of its provisions and a copy of the operating procedures applicable to the work conspicuously in such locations as to insure that employees working in or frequenting radiation areas will observe these documents on the way to and from their place of employment, or shall keep such documents available for examination of employees upon request.

(j) Storage of radioactive materials.

Radioactive materials stored in a nonradiation area shall be secured against unauthorized removal from the place of storage.

(k) Waste disposal.

No employer shall dispose of radioactive material except by transfer to an authorized recipient, or in a manner approved by the Atomic Energy Commission or a State named in paragraph (p)(3) of this section.

(l) Notification of incidents.

(1) **Immediate notification.** Each employer shall immediately notify the Assistant Secretary of Labor or his duly authorized representative, for employees not protected by the Atomic Energy Commission by means of 10 CFR Part 20; paragraph (p)(2) of this section, or the requirements of the laws and regulations of States named in paragraph (p)(3) of this section, by telephone or telegraph of any incident involving radiation which may have caused or threatens to cause:

(i) Exposure of the whole body of any individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to 150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation; or

(ii) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limit specified for such materials in Table II of Appendix B to 10 CFR Part 20.

(iii) A loss of 1 working week or more of the operation of any facilities affected; or

(iv) Damage to property in excess of $100,000.

(2) **Twenty-four hour notification.** Each employer shall within 24 hours following its occurrence notify the Assistant Secretary of Labor or his duly authorized representative for employees not protected by the Atomic Energy Commission by means of 10 CFR Part 20; paragraph (p)(2) of this section, or the requirements of the laws and applicable regulations of States named in paragraph (p)(3) of this section, by telephone or telegraph of any incident involving radiation which may have caused or threatens to cause:

(i) Exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation; or

(ii) A loss of 1 day or more of the operation of any facilities; or

(iii) Damage to property in excess of $10,000.

(m) Reports of overexposure and excessive levels and concentrations.

(1) In addition to any notification required by paragraph (1) of this section each employer shall make a report in writing within 30 days to the Assistant Secretary of Labor or his duly authorized representative, for employees not protected by the Atomic Energy Commission by means of 10 CFR Part 20; or under paragraph (p)(2) of this section, or the requirements of the laws and regulations of States named in paragraph (p)(3) of this section, of each exposure of an individual to radiation or concentrations of radioactive material in excess of any applicable limit in this section. Each report required under this subparagraph shall describe the extent of exposure of persons to radiation or to radioactive material; levels of radiation and concentration of radioactive material involved, the cause of the exposure, levels of concentrations; and corrective steps taken or planned to assure against a recurrence.

(2) In any case where an employer is required pursuant to the provisions of this paragraph to report to the U.S. Department of Labor any exposure of an individual to radiation or to concentrations of radioactive material, the employer shall also notify such individual of the nature and extent of exposure. Such notice shall be in writing and shall contain the following statement: "You should preserve this report for future reference."

(n) Records.

(1) Every employer shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each of his employees of his individual exposure on at least an annual basis.

(2) Every employer shall maintain records in the same units used in tables in paragraph (b) of this section and Appendix B to 10 CFR Part 20.

(o) Disclosure to former employee of individual employee's record.

(1) At the request of a former employee an employer shall furnish to the employee a report of the employee's exposure to radiation as shown in records maintained by the employer pursuant to paragraph (n)(1) of this section. Such report shall be furnished within 30 days from the time the request

is made, and shall cover each calendar quarter of the individual's employment involving exposure to radiation or such lesser period as may be requested by the employee. The report shall also include the results of any calculations and analysis of radioactive material deposited in the body of the employee. The report shall be in writing and contain the following statement: "You should preserve this report for future reference."

(2) The former employee's request should include appropriate identifying data, such as social security number and dates and locations of employment.

(p) Atomic Energy Commission licensees—AEC contractors operating AEC plants and facilities—AEC agreement State licensees or registrants.

(1) Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended, under a license issued by the Atomic Energy Commission and in accordance with the requirements of 10 CFR Part 20 shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

(2) AEC contractors operating AEC plants and facilities: Any employer who possesses or uses source material, byproduct material, special nuclear material, or other radiation sources under a contract with the Atomic Energy Commission for the operation of AEC plants and facilities and in accordance with the standards, procedures, and other requirements for radiation protection established by the Commission for such contract pursuant to the Atomic Energy Act of 1954 as amended (42 U.S.C. 2011 et seq.), shall be deemed to be in compliance with the requirements of this section with respect to such possession and use.

(3) AEC-agreement State licensees or registrants:

(i) **Atomic Energy Act sources.** Any employer who possesses or uses source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by, a State which has an agreement in effect with the Atomic Energy Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, unless the Secretary of Labor, after conference with the Atomic Energy Commission, shall determine that the State's program for control of these radiation sources is incompatible with the requirements of this section. Such agreements currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho, Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

(ii) **Other sources.** Any employer who possesses or uses radiation sources other than source material, byproduct material, or special nuclear material, as defined in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.), and has either registered such sources with, or is operating under a license issued by a State which has an agreement in effect with the Atomic Energy Commission pursuant to section 274(b) (42 U.S.C. 2021(b)) of the Atomic Energy Act of 1954, as amended, and in accordance with the requirements of that State's laws and regulations shall be deemed to be in compliance with the radiation requirements of this section, insofar as his possession and use of such material is concerned, provided the State's program for control of these radiation sources is the subject of a currently effective determination by the Assistant Secretary of Labor that such program is compatible with the requirements of this section. Such determinations currently are in effect only in the States of Alabama, Arkansas, California, Kansas, Kentucky, Florida, Mississippi, New Hampshire, New York, North Carolina, Texas, Tennessee, Oregon, Idaho, Arizona, Colorado, Louisiana, Nebraska, Washington, Maryland, North Dakota, South Carolina, and Georgia.

(q) [Reserved]

(r) Radiation standards for mining.

(1) For the purpose of this paragraph, a "working level" is defined as any combination of radon daughters in 1 liter of air which will result in the ultimate emission of 1.3x10^5 million electron volts of potential alpha energy. The numerical value of the "working level" is derived from the alpha energy released by the total decay of short-lived radon daughter products in equilibrium with 100 picocuries of radon 222 per liter of air. A working level month is defined as the exposure received by a worker breathing air at one working level concentration for 4⅓ weeks of 40 hours each.

(2) Occupational exposure to radon daughters in mines shall be controlled so that no individual will receive an exposure of more than 2 working level months in any calendar quarter and no more than 4 working level months in any calendar year. Actual exposures shall be kept as far below these values as practicable.

(3)

(i) For uranium mines, records of environmental concentrations in the occupied parts of the mine, and of the time spent in each area by each person involved in an underground work shall be established and maintained. These records shall be in sufficient detail to permit calculations of the exposures, in units of working level months, of the individuals and shall be available for inspection by the Secretary of Labor or his authorized agents.

(ii) For other than uranium mines and for surface workers in all mines, subdivision (i) of this subparagraph will be applicable: *Provided, however,* That if no environmental sample shows a concentration greater than 0.33 working level in any occupied part of the mine, the maintenance of individual occupancy records and the calculation of individual exposures will not be required.

(4)

(i) At the request of an employee (or former employee) a report of the employee's exposure to radiation as shown in records maintained by the employer pursuant to subparagraph (3) of this paragraph, shall be furnished to him. The report shall be in writing and contain the following statement:

> This report is furnished to you under the provisions of the U.S. Department of Labor, Ionizing Radiation Safety and Health Standards (29 CFR 1910.96(r)). You should preserve this report for future reference.

(ii) The former employee's request should include appropriate identifying data, such as social security number and dates and locations of employment.

1910.97—NONIONIZING RADIATION

(a) Electromagnetic radiation.

(1) Definitions applicable to this paragraph.

(i) The term "electromagnetic radiation" is restricted to that portion of the spectrum commonly defined as the radio frequency region, which for the purpose of this specification shall include the microwave frequency region.

(ii) Partial body irradiation. Pertains to the case in which part of the body is exposed to the incident electromagnetic energy.

(iii) Radiation protection guide. Radiation level which should not be exceeded without careful consideration of the reasons for doing so.

(iv) The word "symbol" as used in this specification refers to the overall design, shape, and coloring of the rf radiation sign shown in figure G-11.

(v) Whole body irradiation. Pertains to the case in which the entire body is exposed to the incident electromagnetic energy or in which the cross section of the body is smaller than the cross section of the incident radiation beam.

(2) Radiation protection guide.

(i) For normal environmental conditions and for incident electromagnetic energy of frequencies from 10 MHz to 100 GHz, the radiation protection guide is 10 mW/cm.^{2} (milliwatt per square centimeter) as averaged over any possible 0.1-hour period. This means the following:

Power density: 10 mW./cm.^{2} for periods of 0.1-hour or more.
Energy density: 1 mW.-hr./cm.^{2} (milliwatt hour per square centimeter) during any 0.1-hour period.

This guide applies whether the radiation is continuous or intermittent.

(ii) These formulated recommendations pertain to both whole body irradiation and partial body irradiation. Partial body irradiation must be included since it has been shown that some parts of the human body (e.g., eyes, testicles) may be harmed if exposed to incident radiation levels significantly in excess of the recommended levels.

(3) Warning symbol.

(i) The warning symbol for radio frequency radiation hazards shall consist of a red isosceles triangle above an inverted black isosceles triangle, separated and outlined by an aluminum color border. The words "Warning—Radio-Frequency Radiation Hazard" shall appear in the upper triangle. See figure G-11.

(ii) American National Standard Safety Color Code for Marking Physical Hazards and the Identification of Certain Equipment, Z53.1-1953, shall be used for color specification. All lettering and the border shall be of aluminum color.

(iii) The inclusion and choice of warning information or precautionary instructions is at the discretion of the user. If such information is included it shall appear in the lower triangle of the warning symbol.

(4) Scope. This section applies to all radiations originating from radio stations, radar equipment, and other possible sources of electromagnetic radiation such as used for communication, radio navigation, and industrial and scientific purposes. This section does not apply to the deliberate exposure of patients by, or under the direction of, practitioners of the healing arts..

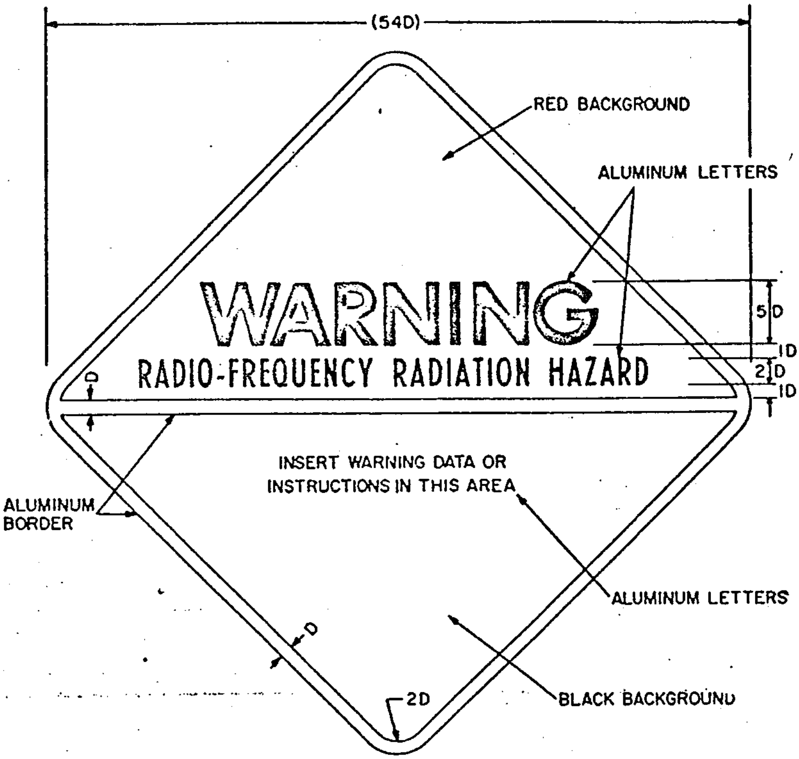
1910.98—EFFECTIVE DATES

(a) The provisions of this Subpart G shall become effective on August 27, 1971, except as provided in the remaining paragraphs of this section.

(b) The following provisions shall become effective on February 15, 1972:

§ 1910.94 (a)(2)(iii), (a)(3), (a)(4), (b), (c)(2), (c)(3), (c)(4), (c)(5), (c)(6)(i), (c)(6)(ii), (d)(1)(ii), (d)(3), (d)(4), (d)(5), and (d)(7).

(c) Notwithstanding anything in paragraph (a), (b), or (d) of this section, any provision in any other section of this subpart which contains in itself a specific effective date or time limitation shall become effective on such date


(54D)
RED BACKGROUND
ALUMINUM LETTERS
WARNING
RADIO-FREQUENCY RADIATION HAZARD
5D
1D
2D
1D
D
ALUMINUM BORDER
INSERT WARNING DATA OR INSTRUCTIONS IN THIS AREA
ALUMINUM LETTERS
D
2D
BLACK BACKGROUND

1. Place handling and mounting instructions on reverse side.
2. D = Scaling unit.
3. Lettering: Ratio of letter height to thickness of letter lines.

Upper triangle :	5 to 1	Large
	6 to 1	Medium
Lower triangle	4 to 1	Small
	6 to 1	Medium

4. Symbol is square, triangles are right-angle isosceles.

Fig. G-11
Radio-Frequency Radiation Hazard Warning Symbol

or shall apply in accordance with such limitation.

(d) Notwithstanding anything in paragraph (a) of this section, if any standard in 41 CFR Part 50-204, other than a national consensus standard incorporated by reference in § 50-204.2(a)(1), is or becomes applicable at any time to any employment and place of employment, by virtue of the Walsh-Healey Public Contracts Act, or the Service Contract Act of 1965, or the National Foundation on Arts and Humanities Act of 1965, any corresponding established Federal standard in this Subpart G which is derived from 41 CFR Part 50-204 shall also become effective, and shall be applicable to such employment and place of employment, on the same date.

1910.99—SOURCES OF STANDARDS

Section	*Source*
1910.94(a)	ANSI N2.3-1967, Immediate and Safe Practices, of Abrasive Blasting Operations.
1910.94(b)	ANSI Z43.1-1966, Ventilation Control of Grinding, Polishing, and Buffing Operations.
1910.94(c)	ANSI Z9.3-1970, Safety Code for the Design, Construction and Ventilation of Spray Finishing Operations.
1910.94(d)	ANSI Z9.1-1969, Safety Code for Ventilation and Operation of Open-Surface Tanks.
1910.95	41 CFR 50-204.10.
1910.96(a) through (e) and (g) through (r).	41 CFR 50-204.20.
1910.98(f)	ANSI N2.3-1967, Immediate Evacuation Signal for Use in Industrial Installations Where Radiation Exposure May Occur.
1910.97	ANSI C95.1-1966, Safety Level of Electromagnetic Radiation with Respect to Personnel and American National Standards Institute C95.2-1966, Radio Frequency Radiation Hazard and Warning Signal.

1910.100—STANDARDS ORGANIZATIONS

Specific standards of the following organizations have been referenced in this subpart. Copies of the standards may be obtained from the issuing organization.

American Conference of Governmental Industrial Hygienists, 1014 Broadway, Cincinnati, OH 45202.
American National Standards Institute, 1430 Broadway, New York, NY 10018.
National Fire Protection Association, 60 Batterymarch Street, Boston, MA 02110.

1910.145—SPECIFICATIONS FOR ACCIDENT PREVENTION SIGNS AND TAGS

(a) Scope.

(1) These specifications apply to the design, application, and use of signs or symbols (as included in paragraphs (c) through (e) of this section) intended to indicate and, insofar as possible, to define specific hazards of a nature such that failure to designate them may lead to accidental injury to workers or the public, or both, or to property damage. These specifications are intended to cover all safety signs except those designed for streets, highways, railroads, and marine regulations. These specifications do not apply to plant bulletin boards or to safety posters.

(2) All new signs and replacements of old signs on or after August 31, 1971, shall be in accordance with these specifications.

(b) Definitions.

As used in this section, the word "sign" refers to a surface on which letters or other markings appear, prepared for the warning of, or safety instructions of, industrial workers or members of the public who may be exposed to hazards. Excluded from this definition, however, are news releases, displays commonly known as safety posters, and bulletins used for employee education.

(c) Classification of signs according to use.

(1) Danger signs.

(i) Danger signs should be used only where an immediate hazard exists. There shall be no variation in the type of design of signs posted to warn of specific dangers and radiation hazards.

(ii) All employees shall be instructed that danger signs indicate immediate danger and that special precautions are necessary.

(2) Caution signs.

(i) Caution signs shall be used only to warn against potential hazards or to caution against unsafe practices.

(ii) All employees shall be instructed that caution signs indicate a possible hazard against which proper precaution should be taken.

(3) Safety instruction signs. Safety instruction signs shall be used where there is a need for general instructions and suggestions relative to safety measures.

(d) Sign design and colors.

(1) Design features. The colors, proportions, and location of the identification panels on each sign shall be in accordance with this paragraph. All signs shall be furnished with rounded or blunt corners and shall be free from sharp edges, burrs, splinters, or other sharp projections. The ends or heads of bolts or other fastening devices shall be located in such a way that they do not constitute a hazard. When conditions warrant the use of a sign size not covered in the following tables, the ratio of the depth of the identifying panel (Danger, Caution, etc.) to the width of the sign shall be as established in Tables J–1 to J–4.

(2) Danger signs.

(i) The colors red, black, and white shall be those of opaque glossy samples as specified in Table 1 of Fundamental Specification of Safety Colors for CIE Standard Source "C", American National Standard Z53.1–1967.

(ii) Standard proportions shall be as indicated in Table J–1, and format shall be as in Fig. J–1.

(3) Radiation warning signs.

TABLE J-1—STANDARD PROPORTIONS FOR DANGER SIGNS

Sign size, inches Height Width	Black rectangular panel, inches Height Width	Red oval, inches Height Width	Word danger, height inches	Maximum space available for sign wording, inches
		HORIZONTAL PATTERN		
7 x 10	3¼ x 9⅜	2⅞ x 8½	1 7/16	2¾ x 9⅜
10 x 14	4⅝ x 13⅜	4⅛ x 11⅞	2 1/16	4¼ x 13⅜
14 x 20	6½ x 19⅜	5¾ x 17	2⅞	6¼ x 19⅜
20 x 28	9¼ x 27⅜	8¼ x 23⅞	4⅛	9½ x 27⅜
		UPRIGHT PATTERN		
10 x 7	2⅜ x 6⅜	2⅛ x 5⅞	1 1/16	6⅜ x 6⅜
14 x 10	3¼ x 9⅜	2⅞ x 8½	1 7/16	9½ x 9⅜
20 x 14	4⅝ x 13⅜	4⅛ x 11⅞	2 1/16	14 x 13⅜
28 x 20	6½ x 19⅜	5¾ x 17	2⅞	20¼ x 19⅜

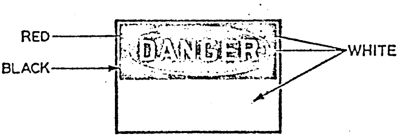


Fig. J-1
Danger Sign

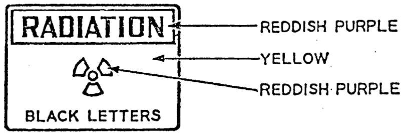


Fig. J-2
Radiation Warning Sign

(i) Standard color of the background shall be yellow; the panel, reddish purple with yellow letters; the symbol, reddish purple; any letters used against the yellow background shall be black. The colors shall be those of opaque glossy samples as specified in Table 1 of American National Standard, Z53.1–1967.

(ii) The standard symbol shall be as in Figure J-3. Method of dimensioning, design, and orientation of the standard symbol (one blade pointed downward and centered on the vertical axis) shall be executed as illustrated. The symbol shall be prominently displayed, and of a size consistent with the size of the equipment or material or area to which it is attached.

(iii) Format shall be as in Figure J-2. Sign proportions shall be the same as those for danger signs in Table J-1.

(4) Caution signs.

(i) Standard color of the background shall be yellow; and the panel, black with yel-

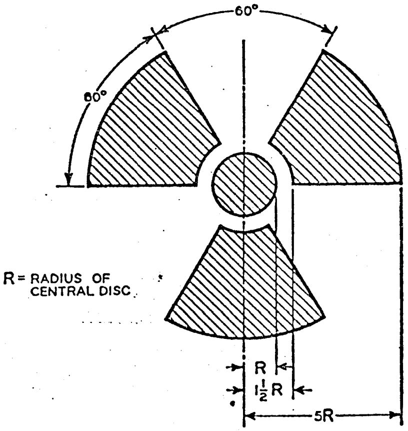
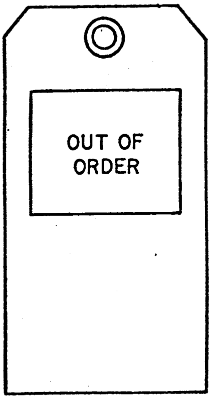
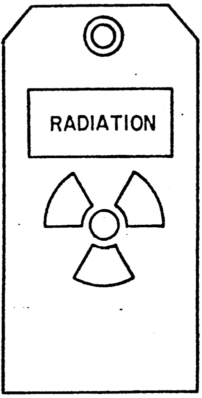


Fig. J-3
Standard Radiation Symbol



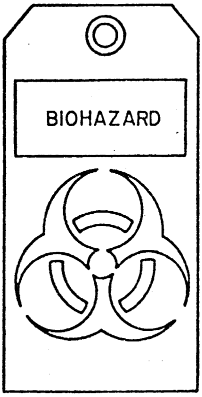
White tag
white letters on
black background

Fig. J-13
Out of Order Tag



Yellow tag
yellow letters in
reddish-purple panel
(Added wording in black
on yellow background)

Fig. J-14
Radiation Tag



White tag
black letters on
fluorescent-orange
background and
symbol

Fig. J-15
Biological Hazard Tag

warn against potential hazards or to caution against unsafe practices. (See Fig. J-12.)

(ii) All employees should be instructed that Caution tags indicate a possible hazard against which proper precautions should be taken.

(6) Out of order tags. Out of Order tags should be used only for the specific purpose of indicating that a piece of equipment, machinery, etc., is out of order and to attempt to use it might present a hazard. (See Fig. J-13.)

(7) Radiation tags.

(i) The standard background for Radiation tags shall be yellow; the panel shall be reddish purple. Any letters used against the yellow background shall be black. The colors shall be those of opaque glossy samples as specified in Table 1, Fundamental Specification of Safety Colors for CIE Standard Source "C" American National Standard Safety Color Code for Marking Physical Hazards and the Identification of Certain Equipment, Z53.1-1967.

(ii) The method of dimension, design, and orientation of the standard symbol (one blade pointed downward and centered on the vertical axis) shall be executed as illustrated in Figure J-14. The symbol shall be prominently displayed and of a size consistent with the size of the equipment or area in which it is to be used.

(8) Biological hazard tags.

(i) The standard background color for the Biological Hazard symbol is optional as

(i) **General.** The requirements of paragraphs (a), (b), (d), (e), and (f) of this section shall be observed.

(ii) **X-ray inspection.** The use of X-rays and radioactive isotopes for the inspection of welded piping joints shall be in conformance with the American National Standard Safety Standard for Non-Medical X-ray and Sealed Gamma-Ray Sources. ANSI Z54.1-1963.

1910.253—SOURCES OF STANDARDS

Sec.	*Source*
1910.251	ANSI Z49.1-1967, Safety in Welding and Cutting.
1910.252	(a) NFPA—51-1969, Welding and Cutting Oxygen Fuel Gas Systems. (b) ANSI Z-49.1 1967, Safety in Welding and Cutting. (c) NFPA 51B 1962, Cutting and Welding Processes. (d) 41 CFR 50-204.7.

1910.254—STANDARDS ORGANIZATIONS

Specific standards of the following organizations have been referenced in this subpart. Copies of the referenced standards may be obtained from the issuing organizations. The names and addresses of the issuing organizations are as follows:

(a) American National Standards Institute (ANSI), 1430 Broadway, New York, NY 10018.

(b) National Fire Protection Association (NFPA), 60 Batterymarch Street, Boston, MA 02110.

(c) Compressed Gas Association, Inc., 500 Fifth Avenue, New York, NY 10036.

(d) American Petroleum Institute, 1801 K Street NW., Washington, DC 20006.

(e) American Welding Society, 345 East 47th Street, New York, NY 10017.

(f) Rubber Manufacturers Association, 444 Madison Avenue, New York, NY 10022.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES,
Research Triangle Park, N.C., June 8, 1977.

Hon. WENDELL H. FORD,
Chairman, Consumer Subcommittee, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The National Institute of Environmental Health Sciences (NIEHS) is pleased to provide you with the detailed material describing the NIEHS effort in radiation research. We have carefully followed the format which you provided with your letter of May 19. We hope these data will be helpful to you as you undertake your comprehensive review.

We are pleased to provide our brief responses.

Question 1 dealt with the effects of changes in public jurisdictions and posture between 1968 and 1977. The formation of new agencies such as the Environmental Protection Agency and the Energy Research and Development Administration with significantly increased regulatory responsibility has not affected our program directly. However, NIEHS has felt obliged to respond in a manner somewhat limited by available resources to additional emphasis and to the need for more research in the area of non-ionizing radiation. Further, with the enactment of the Radiation Control for Health and Safety Act, we recognize the need for additional long-term basic research to support the development of realistic standards.

Question 2 was concerned with the nature of contacts between state groups and NIEHS. Contacts with state radiation professionals is rather limited to occasional responses to requests for general information from both public and private sources at the state level and to participation by NIEHS professional staff in meetings with local health physics societies or with other relevant professional societies.

The third question dealt with the regulation of radiation programs. We understand this to be the coordination of radiation research supported and conducted by the federal government. Each federal agency has generally chosen the research projects and program priorities which respond to their specific mission statements. The general mission of the agency along with the general state of science in this field has dictated the composition of that agency's component of the total federal effort. The Office of Telecommunications Policy (OTP) has done an excellent job of bringing together a compilation of the current research projects in non-ionizing radiation. OTP has however not been able to formally coordinate research programs or to obtain the added resources necessary to fund the additional research needed. We recognize that one of the major problems in coordinating research exists because there are many different and diverse public agencies which have considerable official responsibility, but very small under-supported organizations to carry out the research required to meet their public responsibilities. This phenomenon has in many ways led to a self-imposed coordination activity. In this situation agencies are quite reluctant to duplicate efforts. We believe that the present funding level for all research is far short of that needed to adequately answer existing regulatory questions in a reasonable time. The OTP has indicated in their program analyses that the total federal effort is budgeted at about one-half of that required to fully meet responsibilities. We believe however that money alone will not meet the currently unmet needs. A major element in this effort will be the inducement of sufficient numbers of trained scientists into research activity in electromagnetic radiation effects.

In response to the fourth question we are concerned that there are a number of relatively small research efforts in various agencies which deal with the scientific problems related to radiation. We believe that there exist valid reasons for each of these agencies to have a radiation research activity. However we are concerned that the sum total effect of these activities may be less than their impact if they were aggregated. We would point out however that here would cerainly develop problems for agencies to meet mission requirements if their research capabilities were removed from them. It is doubtful that a single mission oriented agency would have the breadth of interest or the level of mutual confidence to successfully aggregate a radiation research program of the necessary magnitude. It may be possible however to approach this in a basic research agency such as the National Institutes of Health.

We appreciate the opportunity to provide the enclosed factual information to the Committee regarding NIEHS' radiation research effort and further, appreciate the opportunity to discuss our impressions regarding the federal organization of radiation research activities.

Sincerely,

DAVID P. RALL, M.D., Ph. D.,
Director.

IONIZING RADIATION

CODE: IH - In-house; CON - contracts; EM - Extramural

Year	Studies to determine human health effects		Ecological effects-animals and plants		Medical, diagnostic Therapeutic		Other Biological or physical effects	
	Man Years	Funds	Man Years	Funds	Man Years	Funds	Man Years	Funds
1968 IH								
CON								
EM			2.4	11,000	5.4	131,000	3.0	34,000
TOTAL			2.4	11,000	5.4	131,000	3.0	34,000
1969 IH	0.7	30,800						
CON	8.0	307,100						
EM	2.1	26,000	2.4	18,000	5.4	140,000	2.0	28,000
TOTAL	10.8	363,900	2.4	18,000	5.4	140,000	2.0	28,000
1970 IH	1.8	79,200						
CON	13.0	425,900						
EM	2.0	25,000			5.4	148,000	2.0	31,000
TOTAL	16.8	530,100			5.4	148,000	2.0	31,000
1971 IH	2.7	120,800						
CON	15.0	450,800						
EM	3.5	41,000			7.2	203,000	3.9	35,000
TOTAL	21.2	612,600			7.2	203,000	3.9	35,000
1972 IH	2.4	105,600						
CON	15.0	450,800						
EM	2.3	98,000			7.2	252,000	3.8	73,000
TOTAL	19.7	654,400			7.2	252,000	3.8	73,000
1973 IH	2.9	127,600						
CON	16.0	455,000						
EM	2.8	65,000			7.2	267,000	5.9	75,000
TOTAL	21.7	647,600			7.2	267,000	5.9	75,000
1974 IH	2.0	88,000						
CON	18.0	325,000						
EM	3.0	97,000			7.3	284,000	6.9	77,000
TOTAL	18.0	510,000			7.3	284,000	6.9	77,000
1975 IH	2.5	110,000						
CON	8.0	200,000						
EM	7.0	157,000			6.7	312,000	6.1	136,000
TOTAL	17.5	467,00			6.7	312,000	6.1	136,000
1976 IH	2.9	127,600						
CON	0							
EM	6.2	152,000			6.5	361,000	6.4	115,000
TOTAL	9.1	279,600			6.5	361,000	6.4	115,000
1977 IH	2.0	88,000						
CON								
EM	9.0	244,000			6.4	411,000	6.9	165,000
TOTAL	11.0	332,000			6.4	411,000	6.9	165,000
(Est.)								
1978 IH								
CON								
EM	9.7	268,000			6.4	439,000	7.4	170,000
TOTAL	9.7	268,000			6.4	439,000	7.4	170,000

NON-IONIZING RADIATION

CODE: IH - In-house; CON - Contract; EM - Extramural

Microwaves

Year	Studies to determine human health effects	
	Man years	Funds
1969 IH	0	0
CON	0	0
EM	0	0
TOTAL	0	0
1970 IH	0.6	26,400
CON	0	0
EM	0	0
TOTAL	0.6	35,200
1971 IH	1.7	74,800
CON	0	0
EM	0	0
TOTAL	1.7	74,800
1972 IH	3.7	152,800
CON	1.3	51,500
EM	0	0
TOTAL	5.0	214,300
1973 IH	5.3	231,200
CON	1.2	43,200
EM	0	0
TOTAL	6.5	274,400
1974 IH	5.5	239,800
CON	0.5	15,300
EM	0	0
TOTAL	6.0	255,100
1975 IH	4.8	213,400
CON	.5	15,300
EM	3.1	103,900
TOTAL	8.4	332,600
1976 IH	3.7	162,800
CON	0	0
EM	3.1	99,600
TOTAL	6.8	262,400
1977 IH	4.2	184,800
CON	5.0	228,100
EM	3.1	110,400
TOTAL	12.3	523,300
Est. 1978 IH	4.3	190,000
CON	3.2	150,000
EM	3.3	120,000
TOTAL	10.8	460,000

NON-IONIZING RADIATION

CODE: IH - In-house; CON - Contracts, EM - Extramural

Extra Low Frequency

Year	Studies to determine human health effects	
	Man Years	Funds
1968	0	0
1969	0	0
1970	0	0
1971	0	0
1972	0	0
1973	0	0
1974	0	0
1975	0	0
1976 CON TOTAL	2.0 2.0	100,000 100,000
1977 CON TOTAL	2.0 2.0	100,000 100,000
Est. 1978 CON TOTAL	2.0 2.0	100,000 100,000

NON-IONIZING RADIATION

CODE: IH - In-house; CON - Contract; EM - Extramural

Ultraviolet Radiation

Year	Studies to determine human health effects		Medical, Diagnostic, Therapeutic	
	Man Years	Funds	Man Years	Funds
1968 EM TOTAL	8.0 8.0	122,000 122,000	2.0 2.0	31,000 31,000
1969 EM TOTAL	8.4 8.4	122,000 122,000	2.1 2.1	30,000 30,000
1970 EM TOTAL	7.7 7.7	64,000 64,000	1.9 1.9	11,000 11,000
1971 EM TOTAL	7.7 7.7	201,000 201,000	1.6 1.6	46,000 46,000
1972 EM TOTAL	8.8 8.8	156,000 156,000	1.9 1.9	35,000 35,000
1973 EM TOTAL	7.9 7.9	175,000 175,000	1.7 1.7	40,000 40,000
1974 EM TOTAL	9.3 9.3	160,000 160,000	2.1 2.1	55,000 55,000
1975 EM TOTAL	14.1 14.1	237,000 237,000	3.3 3.3	56,000 56,000
1976 EM TOTAL	10.7 10.7	240,000 240,000	2.4 2.4	56,000 56,000
1977 EM TOTAL	11.0 11.0	248,000 248,000	2.5 2.5	58,000 58,000
Est. 1978 EM TOTAL	11.0 11.0	250,000 250,000	2.5 2.5	60,000 60,000

NON-IONIZING RADIATION

CODE: IH - In-house; CON - Contract; EM - Extramural

LASER

Year	Studies to determine human health effects	
	Man Years	Funds
1968 EM	0	0
1969 EM	2.0	27,300
TOTAL	2.0	27,300
1970 EM	2.05	23,900
TOTAL	2.05	23,900
1971 EM	2.25	27,700
TOTAL	2.25	27,700
1972 EM	3.3	34,500
TOTAL	3.3	34,500
1973 EM	2.85	34,500
TOTAL	2.85	34,500
1974 EM	2.65	29,500
TOTAL	2.65	29,500
1975 EM	2.85	41,400
TOTAL	2.85	41,400
1976 EM	3.85	38,000
TOTAL	3.85	38,000
1977 EM	3.75	39,400
TOTAL	3.75	39,400
Est. 1978 EM	3.8	40,000
TOTAL	3.8	40,000

NON-IONIZING RADIATION

CODE: IH - In-house; CON - Contracts; EM - Extramural

Whole Light

Year	Studies to determine human health effects	
	Man Years	Funds
1968 EM TOTAL	3.4 3.4	53,700 53,700
1969 EM TOTAL	3.6 3.6	51,200 51,200
1970 EM TOTAL	3.4 3.4	50,500 50,500
1971 EM TOTAL	5.0 5.0	112,000 112,000
1972 EM TOTAL	5.0 5.0	112,000 112,000
1973 EM TOTAL	5.5 5.5	148,100 148,100
1974 EM TOTAL	4.3 4.3	106,600 106,600
1975 EM TOTAL	4.3 4.3	106,000 106,000
1976 EM TOTAL	4.5 4.5	118,100 118,100
1977 EM TOTAL	4.4 4.4	110,700 110,700
Est. 1978 EM TOTAL	4.5 4.5	120,700 120,700

PROJECT DESCRIPTIONS—FISCAL YEAR 1969

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–69

Project title: Development of a Respiratory Tract Dose Model for Uranium Miners.

Studies to determine human health effects.

Total man-years. 0.45. Funding level: $19,800.

Project description: To develop a respiratory tract dose model that will provide reliable estimates of the dose to the basal cells of the bronchial epithelium in the case of inhalation of alpha emitters. A theoretical approach has been taken that requires identification of the relations between the important parameters involved in the assessment of the dose to the respiratory tract due to inhalation of alpha emitters. The model must be based to the extent possible on actual dose-effect data.

Ionizing Radiation—Project I2–69

Project title: Range and Linear Energy Transfer of Alpha Particles in Tissue.

Studies to determine human health effects.

Total man-years: 0.25. Funding level: $11,000.

Project description: To determine the range and linear energy transfer of alpha particles in tissue and to investigate the connection between those energy loss characteristics and biological effects.

Ionizing Radiation—Project I3–69

Project title: Research on the "Combined Effects of Inhalation of Uranium Ore Dust and Radon Daughters with Cigarette Smoke or Diesel Exhaust Fumes on the Lungs of Dogs and Hamsters." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Studies to determine human health effects.

Funding level: $159,000.

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters are to be exposed to the following combinations: (*a*) Radon daughters on room air nuclei, (*b*) radon daughters on carnotite ore dust plus diesel exhaust fumes; (*c*) diesel and exhaust fumes alone.

Analysis and control of concentrations of radon and daughters, composition of ore dust, and concentrations of other toxic agents in the diesel oil exhaust fumes will be made by the most advanced techniques available. After being exposed to alpha particle irradiation to predetermined cumulative dosage levels comparable to the WLM exposures of high-level exposed miners, the animals will be maintained for life for the observation of pathological changes, particularly lung cancer.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

(*a*) Dogs exposed to radon and daughters on carnotic ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocuries per liter;

(*b*) Dogs exposed to radon plus daughters on ore as in (a), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours);

(*c*) Two shifts of smoking only, 10 cigarettes per day as in (b).

Regular clinical, radiological, radiographic, and hematological examinations will be made during and after the smoking and radon exposures. The dogs, except for one in each group to be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Ionizing Radiation—Project I4–69

Project title: Radon Progeny Inhalation Exposures to Uranium Miners. (Contract—Colorado State University.)

Studies to determine human health effects.

Funding level: $29,140.

Project description: This research was initiated as part of an integrated program to determine the effects of inhalation of radon and its daughters upon the induction of bronchogenic carcinoma in uranium miners. Forty actively working uranium miners were selected from two mines on the Colorado plateau along with ten control subjects residing in the area who had no known occupational exposure to radon progeny or mine environments. The miners were equipped with personal dosimeters consisting of a battery-operated air sampling pump and a thermoluminescent dosimeter (TLD) worn on the miner's hat and designed to sample and measure the radioactivity in the air which the miner actually breathed. Blood and whisker samples were collected on a regular basis for measurement of polonium-210 and lead-210 to determine the correlation between the measured Working Level Month (WLM) exposures to radon progeny and the subsequent deposition of long-lived radioactive decay products in the whiskers. The objective was to develop a reliable personal dosimeter and a reliable bioassay procedure that would indicate cumulative exposures over definite time periods.

Ionizing Radiation—Project I5–69

Project title: Studies of Uranium Miner Hazards Associated with Radon. (Contract—University of Rochester School of Medicine.)

Studies to determine human health effects.

Funding level: $119,000

Project description: In five separate but closely interrelated projects, senior scientists are conducting the following studies:

Project A—Effects on Dogs of Radon Decay Products (Donald Morken).

Project B–1—Measurement of ^{210}Pb Effective Half-Life in Dogs (John Hursh).

Project B–2—The Transport of ^{212}Pb from the Lung in Man (John Hursh).

Project C—Research on Attachment of Radon Decay Projects to Airborne Particles (T.T. Mercer).

Project D—Methods for Improved Bioassay of ^{210}Pb Body Burdens by Determination of ^{210}Pb and ^{210}Po in Urine and Feces (W.F. Bale and R.W. Helmkamp).

Project E—A Study of Quantitation Relationships Between Exposure to Radon and Radon daughters, as deduced from Exposure History and Various Experimentally Measured Parameters, and the Probability of Lung Cancer Development in Man and Experimental Animals (H.A. Blair).

PROJECT DESCRIPTIONS—FISCAL YEAR 1970

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–70

Project title: "Respiratory Tract Dose Model for Uranium Miners."

Studies to determine human health effects.

Total man-years: 0.9. Funding level: $39,600.

Project description: The objective of this project is to develop a respiratory tract dose model that will provide reliable estimates of the dose of radiation to the basal cells of the bronchial epithelium of the respiratory tract in the case of inhalation of alpha emitters. The ideal method would be to calculate the dose to the basal cells in each anatomical region of the respiratory tract. This method requires a detailed description of the exposure atmosphere, a detailed respiratory tract model, accurate techniques of deposition calculation and an accurate analysis of the effects of clearance.

Ionizing Radiation—Project I2–70

Project title: "Energy Loss Characteristics of Radiation in Matter."

Studies to determine human health effects.

Total man years: 0.6. Funding level: $26,400.

Project description: The objectives of this project are to obtain more information on the main interactions of ionizing radiation with matter, such as ionization and excitation with molecules, such as the effect of the penetrating radiation upon molecular bonds. Such information will be basic to further analysis of the connections between physical energy loss and absorption processes and biological effects.

Ionizing Radiation—Project I3–70

Project title: "Interagency Review of the Health Hazards of Uranium Mining—Comparison of Experimental to Empirical Results."

Collection and/or analysis of health data.

Total man-years: 0.3. Funding level: $13,200.

Project description: This project is part of a Federal, Interagency Review of the health hazards of uranium mining. Scientists from all the federal agencies are participating in providing information for the review and in reviewing the total body of information available on radiogenic lung cancer. The sub-group dealing with radiogenic lung cancer has identified responsible agencies and due dates for the various parts of the review. The NIEHS is the responsible agency for a comparison of empirical and experimental information on radiogenic lung cancer.

Ionizing Radiation—Project I4–70

Project title: Research on the "Combined Effects of Inhalation of Uranium Ore Dust and Radon Daughters with Cigarette Smoke or Diesel Exhaust Fumes on the Lungs of Dogs and Hamsters." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Studies to determine human health effects.

Funding level: $276,810.

Project description: As a major part of na integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters are to be exposed to the following combinations: (*a*) Radon daughters on room air nuclei; (*b*) radon daughters and carnotite ore dust; (*c*) diesel engine exhaust alone; and (*d*) diesel exhaust fumes, radon daughters, and ore dust.

Analysis and control of concentrations of radon and daughters, composition of ore dust, and concentrations of other toxic agents in the diesel oil exhaust fumes will be made by the most advanced techniques available. After being exposed to alpha particles irradiation to predetermined cumulative dosage levels comparable to the WLM exposures of high-level exposed miners, the animals will be maintained for life for the observation of pathological changes, particularly lung cancer.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

(*a*) Dogs exposed to radon daughters on carnotite ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocuries per liter.

(*b*) Dogs exposed to radon plus daughters on ore as in (*a*), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours).

(*c*) Two shifts of smoking only, 10 cigarettes per day as in (*b*).

Regular clinical, radiological, radiographic, and hematological examinations will be made during and after the smoking and radon exposures. The dogs, except for one in each group to be sacrified for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Ionizing Radiation—Project I5–70

Project title: "Radon Progeny Inhalation Exposures to Uranium Miners." (Contract—Colorado State University.)

Studies to determine human health effects.

Funding level: $30,010.

Project description: This research was initiated as part of an integrated program to determine the effects of inhalation of radon and its daughters upon the induction of bronchogenic carcinoma in uranium miners. Forty actively working uranium miners were selected from two mines on the Colorado plateau along with ten control subjects residing in the area who had no known occupational exposure to radon progeny or mine environments. The miners were equipped with personal dosimeters consisting of a battery-operated air sampling pump and a thermoluminescent dosimeter (TLD) worn on the miner's hat and designed to sample and measure the radioactivity in the air which the miner actually breathed. Blood and whisker samples were collected on a regular basis for measurement of polonium-210 and lead-210 to determine the correlation between the measured Working Level Month (WLM) exposure to radon progeny and the subsequent deposition of long-lived radioactive decay products in the whiskers. The objective was to develop a reliable personal dosimeter and a reliable bioassay procedure that would indicate cumulative exposures over definite time periods.

Ionizing Radiation—Project I6–70

Project title: "Uranium Mining—Health Hazards Associated with Radon Daughters." (Contract—University of Rochester School of Medicine.)

Studies to determine the human health effects.

Funding level: $119,000.

Project description: In five separate but closely interrelated projects, senior scientists are conducting the following studies:

Project A—Dr. Donald Morken is exposing dogs to radon and radon daughters on room air nuclei. The magnitude and intensity of exposure versus early histopathological effects are important initially.

Project B—Dr. John Hursh is studying the bone and tissue distribution of ^{210}Pb as well as excretion of ^{210}Pb and ^{210}Po using dogs exposed in Project A.

Project B–2—Dr. Hursh has measured the transport time of ^{212}Pb from human lungs.

Project C—Dr. Thomas Mercer is studying the attachment of radon decay product atoms to particles and assists Hursh and Morken in characterizing the radon daughters carrying aerosols.

Project D—Dr. R. W. Helmkamp and Dr. W. F. Bale are developing new techniques for the measurement of ^{210}Po and ^{210}Pb in urine.

Project E—Dr. H. A. Blair is conducting a theoretical study of initiating doses and latent periods for the induction of lung cancer in uranium miners.

Nonionizing Radiation (Microwaves)—Project N1–70

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-year: 0.60. Funding level: $26,400.

Project description: The objectives of this project are to develop a microwave exposure system for biological material which has a well-defined, uniform field characteristic, to study the mechanism of interaction of microwave radiation with matter, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave field in a small laboratory space. At present, it is difficult to accurately measure low-level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermoluminescence, chemical recations, liquid crystals, and photographic film are some of the techniques which will be investigated.

PROJECT DESCRIPTIONS—FISCAL YEAR 1971

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–71

Project title: "Respiratory Tract Dose Model for Uranium Miners."

Study to determine human health effects.

Total man-years: 1.2. Funding level: $52,800.

Project description: The objective of this project is to develop a respiratory tract dose model that will provide reliable estimates of the dose of radiation to the basal cells of the bronchial epithelium of the respiratory tract in the case of inhalation of alpha emitters. Calculation of the dose to the basal cells in each anatomical region of the respiratory tract requires a detailed description of the exposure atmosphere, a detailed respiratory tract model, accurate techniques of depositions calculation and an accurate analysis of the effects of clearance.

Ionizing Radiation—Project I2–71

Project title: "Energy Loss Characteristics of Radiation in Matter."

Study to determine human health effects.

Total man-years: Funding level: $44,000.

Project description: The objectives of this project are to obtain more information on the main interactions of ionizing radiation with matter, such as ionization and excitation of atoms and molecules, and the more subtle interaction of radiation with molecules, such as the effect of the penetrating radiation upon molecular bonds. Such information will be basic to further analysis of the connections between physical energy loss and absorption processes and biological effects. The measurement of the energy loss of radiation is accomplished by using a solid state radiation spectrometer. The complete spectrometer consists of a measurement chamber containing an alpha, beta or gamma radiation source, multiple samples of the material to be studies and a solid state radiation detector. The doses and dose rates of alpha, beta and gamma radiation can be varied at will by adjusting the source-absorber geometry; and the solid state spectrometer allows an accurate determination of the energy loss in the absorber at the same time. This provides an experimental check on theoretical dose estimation. Biological absorbers can be studied with this system.

Ionizing Radiation—Project I3–71

Project title: "Interagency Review of the Health Hazards of Uranium Mining—comparison of Experimental to Empirical Results."

Collection and/or analysis of health data.

Total man-years: 0.5. Funding level: $22,000.

Project description: This project is part of a Federal Interagency Review of the health hazards of uranium mining. Scientists from all the federal agencies are participating in providing information for the review and in reviewing the total body of information available on radiogenic lung cancer. The subgroup dealing with radiogenic lung cancer has identified responsible agencies and due dates for the various parts of the review. The NIEHS is the responsible agency for a comparison of empirical and experimental information on radiogenic lung cancer. The epidemiological studies and toxicological studies were reviewed by other agencies. With their reviews as back-up information, the NIEHS reviewed the theoretical dose calculations and the relationship between the dose calculations and the epidemiological and toxicological results.

Ionizing Radiation—Project I4–71.

Project title: Research on the "Combined Effects of Inhalation of Uranium Ore Dust and Radon Daughters with Cigarette Smoke or Diesel Exhaust Fumes on the Lungs of Dogs and Hamsters." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Studies to determine human health effects.

Funding level: $331,795,

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters are to be exposed to the following combinations: (A) Radon daughters on room air nuclei, (B) radon daughters on carnotite ore dust plus diesel exhaust fumes, and (C) diesel and exhaust fumes alone.

Analysis and control of concentrations of radon and daughters, composition of ore dust, and concentrations of other toxic agents in the diesel oil exhaust fumes will be made by the most advanced techniques available. After being exposed to alpha particle irradiation to predetermined cumulative dosage levels comparable to the WLM exposures of high-level exposed miners, the animals will be maintained for life for the observation of pathological changes, particularly lung cancer.

2. The test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

(a) Dogs exposed to radon and daughters on carnotic ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocuries per liter;

(b) Dogs exposed to radon plus daughters on ore as in (a), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours);

(c) Two shifts of smoking only, 10 cigarettes per day as in (b).

Regular clinical, radiological, radiographic, and hematological examinations will be made during and after the smoking and radon exposures. The dogs, except for one in each group to be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Ionizing Radiation—Project I5–71

Project title: Radon Progeny Inhalation Exposures to Uranium Miners. (Contract—Colorado State University.)

Studies to determine human health effects.

Funding level: $30,010.

Project description: This research was initiated as part of an integrated program to determine the effects of inhalation of radon and its daughters upon the induction of bronchogenic carcinoma in uranium miners. Forty actively working uranium miners were selected from two mines on the Colorado plateau along with ten control subjects residing in the area who had no known occupational exposure to radon progeny or mine environments. The miners were equipped with personal dosimeters consisting of a battery-operated air sampling pump and a thermoluminescent dosimeter (TLD) worn on the miner's hat and designed to sample and measure the radioactivity in the air which the miner actually breathed. Blood and whisker samples were collected on a regular basis for measurement of polonium-210 and lead-210 to determine the correlation between the measured Working Level Month (WLM) exposures to radon progeny and the subsequent deposition and long-lived radioactive decay products in the whiskers. The objective was to develop a reliable personal dosimeter and a reliable bioassay procedure that would indicate cumulative exposures over definite time periods.

Ionizing Radiation—Project I6–71

Project title: "Uranium Mining—Health Hazards Associated with Radon Daughters." (Contract—University of Rochester School of Medicine.)

Studies to determine human health effects.

Funding level: $119,000.

Project description: In five separate but closely interrelated projects, senior scientists are conducting the following studies:

Project A—Dr. Donald Morken has exposed dogs to radon and radon daughters on room air nuclei. The magnitude and intensity of exposure versus early histopathological effects are important initially.

Project B–1—Dr. John Hursh is studying the bone and tissue distribution of ^{210}Pb as well as excretion of ^{210}Pb and ^{210}Po using dogs exposed in Project A.

Project B–2—Dr. Hursh has measured the transport time of ^{212}Pb from human lungs.

Project C—Dr. Thomas Mercer has characterized the radon daughter carrying aerosols used in the studies by Morken and Hursh.

Project D—Dr. R. W. Helmkamp and Dr. W. F. Bale developed new techniques for the measurement of ^{210}Po and ^{210}Pb in urine.

Nonionizing Radiation (microwaves)—N1–71

Project title: "Microwave Absorption by Biological Material."

Studies to determine human health effects.

Total man-years: 0.5. Funding level: $22,000.

Project description: The objectives of this project are to determine the absorption of microwave radiation by biological material, to investigate the contribution of cell structure to the absorption, and to attempt to explain the mechanism of interaction between microwaves and the biological material. DNA, RNA, protein, cell cultures and biologically simulated material (alcohol-water solutions) will be exposed to 2450 MHz microwave radiation. The amount of energy absorption will be measured, and the changes in the media will be evaluated with the assistance of the Cell Biology Branch.

Nonionizing radiation (microwaves)—N2–71

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years: 1. Funding level: $44,000.

Project description: The objectives of this project are to develop a microwave exposure system for biological material which has a well-defined, uniform field characteristic; to study the mechanisms of interaction of microwave radiation with matter; and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave exposure system which would generate a uniform, low-level microwave field in a small laboratory space. At present, it is difficult to accurately measure low level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermister and thermocouple detectors, chemical reactions, liquid crystals, and photographic film are some of the techniques which will be investigated.

Nonionizing Radiation (microwaves)—N3–71

Project title: "Variable Frequency Microwave Exposure System."

Other studies: Biological effects are frequency dependent and variable frequency exposure systems are required for biological effects studies.

Total man-years: 0.20. Funding level: $8,800.

Project description: The objective of this project is to design, build, and calibrate a variable frequency exposure system for biological material. Specifications were written for the desired system. A field uniformity at the specimen of 90 percent over a 4 inch diameter circle, a continuous frequency variation in the range of 1 to 10 GHz, and a power level range at the specimen of 0.010 to 10 mM/cm^2 were specified. A complete search of the available microwave components was performed and from these components a system designed. Components for the system are now being ordered.

PROJECT DESCRIPTIONS—FY 1972

IONIZING AND NON-IONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–72

Project title: "Energy Loss Characteristics of Radiation in Matter."

Study to determine human health effects.

Total man-years: 1.2. Funding level: $52,000.

Project description: The objectives of this project are to obtain more information on the main interactions of ionizing radiation with matters, such as ionization and excitation of atoms and molecules, and the more subtle interactions of radiation with molecules, such as the effect of the penetrating radiation upon molecular bonds. Such information will be basic to further analysis of the connection between physical energy loss and absorption processes and biological effects.

Ionizing Radiation—Project I2–72

Project title: "Respiratory Tract Dose Model for Uranium Miners."

Study to determine human health effects.

Total man-years: 1.2. Funding level: $52,800.

Project description: The objective of this project is to develop a respiratory tract dose model that will provide reliable estimates of the dose of radiation to the basal cells of the bronchial epithelium of the respiratory tract in the case of inhalation of alpha emitters. Calculation of the dose to the basal cells in each anatomical region of the respiratory tract requires a detailed description of the exposure atmosphere, a detailed respiratory tract model, accurate techniques of deposition calculation and an accurate analysis of the effects of clearance.

Ionizing Radiation—Project I3–72

Project title: "Uranium Mining—Health Hazards Associated with Radon Daughters." (Contract—University of Rochester School of Medicine.)

Studies to determine the human health effects.

Funding level: $119,000.

Projection description: In five separate but closely interrelated projects, senior scientists have and/or are conducting the following studies:

Project A—Dr. Donald Morken has exposed dogs to radon and radon daughters on room air nuclei. The magnitude and intensity of exposure versus early histopathological effects are important initially.

Project B–1—Dr. John Hursh has studied the bone and tissue distribution of ^{210} Pb as well as excretion of ^{210}Pb and ^{210}Po using dogs exposed in Project A.

Project B–2—Dr. Hursh has measured the transport time of ^{212}Pb from human lungs.

Project C—Dr. Thomas Mercer has characterized the radon daughter carrying aerosols used in the studies by Morken and Hursh.

Project D—Dr. R. W. Helmkamp and Dr. W. F. Bale have developed new techniques for the measurement of ^{210}Po and ^{210}Pb in urine.

Ionizing Radiation—Project I4–72

Project title: Research on the "Combined Effects of Inhalation of Uranium Ore Dust and Radon Daughters with Cigarette Smoke of Diesel Exhaust Fumes on the Lungs of Dogs and Hamsters." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Study to determine the human health effects.

Funding level: $331,795.

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters were exposed to the following combinations:

(*a*) radon daughters on room air nuclei; (*b*) radon daughters and carnotite ore dust; (*c*) diesel engine exhaust alone; (*d*) diesel exhaust fumes, radon daughters and ore dust; and (*e*) carnotite ore dust.

Concentrations of radon and daughters, composition of ore dust and concentrations of other toxic agents in the diesel oil exhaust fumes were carefully controlled. After being exposed to predetermined cumulative dosage levels comparable to the WLM exposures of high-level exposed miners, the animals were maintained for life for the observation of pathological changes, particularly lung cancer.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

(*a*) Dogs exposed to radon and daughters on carnotite ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocuries per liter; with sham smoking;

(*b*) Dogs exposed to radon plus daughters on ore as in (*a*), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours);

Regular clinical, radiological and radiographic examinations will be made ruring and after smoking and radon exposures. The dogs, except for one in each group which will be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Non-ionizing Radiation (Microwaves)—Project N1–72

Project title: "Variable Frequency Microwave Exposure System."

Other studies: Biological effects are frequency dependent and variable frequency exposure systems are required for biological effects studies.

Total man-years: 0.20. Funding level: $8,800.

Project description: The objective of this project is to design, build and calibrate a variable frequency exposure system for biological material. Specifications were written for the desired system. A field uniformity at the specimen of 90 percent over a 4-inch diameter circle, a continuous frequency variation in the range of 1 to 10 GHz and a power level range at the specimen of 0.010 to 10 mW/cm^2 were specified.

Nonionizing Radiation (microwaves)—Project N2–72

Project title: "Microwave Exposure System and Microwave Dosimetry."
Studies to determine human health effects.
Total man-years: 1. Funding level: $44,000.

Project description: The objectives of this project are to develop a microwave exposure system for biological material which has a well-defined, uniform field characteristic, to study the mechanism of interaction of microwave radiation with matter, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave field in a small laboratory space. At present, it is difficult to accurately measure low-level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermoluminescence, chemical reactions, liquid crystals, and photographic film are some of the techniques which will be investigated.

Nonionizing Radiation (microwave)—Project N3–72

Project title: "Microwave Absorption by Biological Material."
Studies to determine human health effects.
Total man-years: 1. Funding level: $44,000.

Project description. The objectives of this project are to determine the absorption of microwave radiation by biological material, to investigate the contribution of cell structure to the absorption and to attempt to explain the mechanism of interaction between microwaves and the biological material. DNA, RNA, protein cell cultures and biologically simulated material (alcohol-water solutions) will be exposed to 2450 MHz microwave radiation. The amount of energy absorption will be measured, and the changes in the media will be evaluated.

Nonionizing Radiation—Project N4–72

Project title: "Effects of 2450 MHz Microwave Radiation on Biological Material."
Studies ~~to determine~~ human health effects.
Total man-years: 1.2. Funding level: $52,800.

Project description: The objectives of this project are to determine how 2450 MHz microwave radiation interacts with biological material, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Several strains of bacteria and one bacteriophage have been exposed to 2450 MHz microwaves at power levels sufficient to maintain a temperature of 37°C. Growth rate curves and bacteriophage lysis time have been compared in exposed and control situations. DNA, other cell components and tissue culture cells may be exposed and studied later.

Nonionizing Radiation (microwave)—Project N5–72

Project title: "Investigation of Microwave Radiation on Neurological Functioning."
Studies to determine human health effects.
Total man-years: 0.1. Funding level: $4,400.

Project description: The project objective is an attempt to determining more fundamental reasons and mechanisms underlying the neurological effects of microwaves by studying the effects on basic neural structures. The hazards of microwave radiation are a priority matter of current concern for NIEHS. The study of biological effects caused by microwave radiation forms the basis for determining safe levels of exposures. Presently, the safe level of continuous exposure in the U.S.A. is 10 mW/cm^2. This is based on one underlying assumption: namely, that the possible damage due to microwave radiation exposure is of a thermal nature. However, many other experiments, especially from Soviet-block nations, report indications of nonthermal, neurological effects like headaches, fatigue, hyperactivity, altered brain wave patterns and changes in the functional state of nerves, e.g., induced transmembrane potentials. These observations occurred at radiation levels below the extant U.S.A. safe levels. The question of the nonthermal influence of microwaves is the principal one in the problems and consequences of the biological effects of microwaves, and it must be resolved before the degree of the hazard posed to man is determined.

Nonionizing Radiation (microwaves)—Project N6–72

Project title: "Study of Microwave Dosimetry" (Contract—University of Michigan).

Studies to determine human health effects.

Funding level: $51,525.

Project description: The objective of the contract is to develop techniques and detectors which can be used to measure the energy absorbed in a biological specimen placed in either the near or far microwave fields of frequencies ranging from 1 to 10 GHz. Small magnetic field probes have been built and calibrated in free space. These probes respond to the intensity of the magnetic field of the electromagnetic wave. Problems have been encountered in calibrating the probes in high dielectric constant materials and at high frequencies. These difficulties are due to the moding of the electromagnetic field in these materials. Therefore, the field in which the probe is placed is not well known. A technique for extrapolating the results to higher dielectric constant materials and higher frequencies has been theorized and will be applied in future work.

PROJECT DESCRIPTIONS—FISCAL YEAR 1973

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–73

Project title: "Energy Loss Characteristics of Radiation in Matter."

Study to determine human health effects.

Total man-years: 1.5. Funding level: $66,000.

Project description: The objectives of this project are to obtain more information on the main interactions of ionizing radiation with matters, such as ionization and excitation of atoms and molecules, and the more subtle interactions of radiation with molecules, such as the effect of the penetrating radiation upon molecular bonds. Such information will be basic to further analysis of the connection between physical energy loss and absorption processes and biological effects. The measurement of the energy loss of radiation is accomplished by using a solid state radiation spectrometer. The complete spectrometer consists of a measurement chamber containing an alpha, beta or gamma radiation source, multiple samples of the material to be studied and a solid state radiation detector. The doses and dose rates of alpha, beta and gamma radiation can be varied at will by adjusting the source-absorber geometry; and the solid state spectrometer allows an accurate determination of the energy loss in the absorber at the same time. This provides an experimental check on theoretical dose estimation. Biological absorbers can be studied with this system.

Ionizing Radiation—Project I2–73

Project title: "Respiratory Tract Dose Model for Uranium Miners."

Study to determine human health effects.

Total man years: 1.4. Funding level: $61,600.

Project description: The objective of this project is to develop a respiratory tract dose model that will provide reliable estimates of the dose of radiation to the basal cells of the bronchial epithelium of the respiratory tract in the case of inhalation of alpha emitters. Calculation of the dose to the basal cells in each anatomical region of the respiratory tract requires a detailed description of the exposure atmosphere, a detailed respiratory tract model, accurate techniques of deposition calculation and an accurate analysis of the effects of clearance.

Ionizing Radiation—Project I3–73

Project title: "Study of the Combined Effects of Smoking and Inhalation of Uranium Ore Dust, Radon Daughters and Diesel Oil Exhaust Fumes in Hamsters and Dogs." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Study to determine the human health effects.

Funding level: $336,000.

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters were exposed to the following combinations: (*a*) Radon daughters on room air nuclei; (*b*) radon daughters and carnotite ore dust; (*c*) diesel engine exhaust alone; (*d*) diesel exhaust fumes, radon daughters and ore dust; and (*e*) carnotite ore dust.

Concentrations of radon and daughters, composition of ore dust and concentrations of other toxic agents in the diesel oil exhaust fumes were carefully controlled. After being exposed to predetermined cumulative dosage levels, the animals were maintained for life for the observation of pathological changes, particularly lung cancer and emphysema.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

(*a*) Dogs exposed to radon and daughters on carnotite ore—exposure for four hours per day, 7 days per week at concentrations of 15 nanocuries per liter; with sham smoking;

(*b*) Dogs exposed to radon plus daughters on ore as in (a), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours);

Regular clinical, radiological and radiographic examinations will be made during and after smoking and radon exposures. The dogs, except for one in each group which will be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Nonionizing Radiation (microwaves)—Project N1–73

Project title: "Variable Frequency Microwave Exposure System."

Other studies: Biological effects are frequency dependent and variable frequency exposure systems are required for biological effects studies.

Total man-years: 0.20. Funding level: $8,800.

Project description: The objective of this project is to design, build, and calibrate a variable frequency exposure system for biological material. Specifications were written for the desired system. A field uniformity at the specimen of 90 percent over a 4 inch diameter circle, a continuous frequency variation in the range of 1 to 10 GHz, and a power level range at the specimen of 0.010 to 10 mW/cm^2 were specified. Many of the biological effects of microwave radiation are frequency dependent. In terms of whole body irradiation, a frequency of 150–1200 MHz affects the internal organs, whereas, a frequency of 10,000 MHz and above affects primarily the skin. Components of cells such as RNA, DNA and protein were found to have maximum absorption of different frequencies. Therefore, it is necessary to have the capability of varying frequency when investigating microwave effects on biological systems. The frequency range of 1 to 10 GHz was chosen because it is within this range of frequencies to which the general population is exposed.

Nonionizing Radiation (microwaves)—Project N2–73

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years: 1.5. Funding level: $66,000.

Project description: The objectives of this project are to develop a microwave exposure system for biological material which has a well-defined, uniform field characteristic, to study the mechanism of interaction of microwave radiation with matter, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave field in a small laboratory space. At present, it is difficult to accurately measure low-level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermoluminescence, chemical reactions, liquid crystals, and photographic film are some of the techniques which will be investigated.

Nonionizing Radiation (microwaves)—Project N3–73

Project title: "Effects of Microwave Radiation on the Embryonic Development of Japanese Quail."

Studies to determine human health effects.

Total man-years: 0.6. Funding level: $26,400.

Project description: The objective of this project is to determine the effects of microwave radiation on differentiating cells systems. Fertilized Japanese quail eggs will be exposed to microwave radiation in the frequency range of 1–10 GHz. The power level will initially be set to maintain a temperature of between 34° and 37° C in the quail egg. At these temperatures any effects due to the microwave radiation exposure should be nonthermal. If effects on cell differentiation is noted at those power density levels, the power level will be decreased until a threshold value is determined. The initial end point for observation of harmful effects will be deformities in the fully developed embryo.

Nonionizing Radiation (microwaves)—Project N4–73

Project title: "Investigation of Non-Thermal Microwave Radiation Effects on Neurological Functioning."

Studies to determine human health effects.

Total man-years: 0.75. Funding level: $33,000.

Project description: The objective of this project is to conduct an investigation into the non-thermal effects of microwave radiation on neurological functioning. The presently accepted working definition of a non-thermal effect is a biological change attributable to irradiation by microwave energy without significant change of body temperature. This definition does not exclude the possibility of specific local heating effects occurring even though there is no change of the overall or average temperature of the organism. To give a possible example for means of illustration: Conceivably, electric current flow in the cerebrospinal fluid could cause localized heating of the central nervous tissue. A change of temperature in the area of the hypothalamus amounting to not more than 0.1°C could provoke a generalized response of the antonomic nervous system. Such a response would be classed non-thermal inasmuch as it would not be a direct physical consequence of the energy input delivered by the irradiation.

Nonionizing Radiation (microwaves)—Project N5–73

Project title: "Effects of 2450 MHz Microwave Radiation on Biological Material."

Studies to determine human health effects.

Total man-years: 2.2. Funding level: $96,800.

Project description: The objectives of this project are to determine how 2450 MHz microwave radiation interacts with biological material, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Several strains of bacteria and one bacteriophage have been exposed to 2450 MHz microwaves at power levels sufficient to maintain a temperature of 37°C. Growth rate curves and bacteriophage lysis time have been compared in exposed and control situations. DNA, other cell components and tissue culture cells may be exposed and studied later.

Nonionizing Radiation (microwaves)—Project N6–73

Project title: "Study of Microwave Dosimetry." (Contract—Georgia Institute of Technology.)

Studies to determine human health effects.

Funding level: $33,155.

Project description: The objective of the contract is to develop techniques and detectors which can be used to measure the energy absorbed in a biological specimen placed either in the near or far microwave fields of frequencies ranging from 1 to 10 GHz. Georgia Institute of Technology has developed the technology to fabricate microwave detectors using a pyroelectric crystal (triglycine sulfate): A probe has been built and supplied to us which has good sensitivity at 4–10 GHz. Below 4–10 GHz it is necessary to add an absorbing material to the crystal to provide adequate sensitivity. The probe must be placed in a modulated field due to the fact that the probe measures a rate of change in temperature rather than an absolute temperature. Attempts to modulate the probe electronically rather than the incoming field has proved unfruitful. Also the miniaturization of the probe from the 0.5 cm × 0.5 cm has encountered difficulty. The sensitivity of the probe decreases rapidly with decreasing size.

Nonionizing Radiation (microwaves)—Project N7–73

Project title: "A Study of Microwave-Neuron Interaction." (Contract—Drake University.)

Studies to determine human health effects.

Funding level: $9,947.

Project description: The objective of this contract is to determine how microwave energy within the 0.1 to 3.0 GHz frequency range interacts with the human nervous system. There are two basic tasks being undertaken on this project: (*a*) Conduct studies aimed at determining the appropriate equivalent circuit of a neuron at microwave frequencies, and (*b*) develop instrumentation and measure induced transmembrane potential or any change in the firing pattern or activity of isolated nerve cells subjected to microwave irradiation.

PROJECT DESCRIPTIONS—FISCAL YEAR 1974

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–74

Project title: "Theoretical Basis of Dose-Response Relationships."

Studies to determine human health effects.

Total man-years: 2. Funding level: $88,000.

Project description: The objective of this project is to develop a mathematical-theoretical model of the effects of ionizing radiation at the cellular level. Experimental and theoretical approaches are being developed. Experimental systems incorporating spectrometry systems have designed to facilitate the delivery of measured doses of alpha, beta or gamma radiation to cell cultures. A theoretical treatment, built upon data from the literature, is being used to focus the experimental work and to speculate on the nature of dose-response relationships under low-dose, low-dose rate conditions.

Ionizing Radiation—Project I2–74

Project title: "Study of the Combined Effects of Smoking and Inhalation of Uranium Ore Dust, Radon Daughters and Diesel Oil Exhaust Fumes in Hamsters and Dogs." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Study to determine the human health effects.

Funding level: $325,000.

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters were exposed to the following combinations: (*a*) Radon daughters on room air nuclei; (*b*) radon daughters and carnotite ore dust; (*c*) diesel engine exhaust alone; (*d*) diesel exhaust fumes, radon daughters and ore dust; and (*e*) carnotite ore dust.

Concentrations of radon and daughters, composition of ore dust and concentrations of other toxic agents in the diesel oil exhaust fumes were carefully controlled. After being exposed to predetermined cumulative dosage levels, the animals were maintained for life for the observation of pathological changes, particularly lung cancer and emphysema.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking, studies were initiated on three groups of 18 dogs as described below:

a. Dogs exposed to radon and daughters on carnotite ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocries per liter; with sham smoking;

b. Dogs exposed to radon plus daughters on ore as in (a), plus two working shifts of smoking (total of 10 cigarettes per day with resting on alternate hours);

Regular clinical, radiological and radiographic examinations will be made during and after smoking and radon exposures. The dogs, except for one in each group which will be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Nonionizing Radiation (microwaves)—Project N1–74

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years: 2.2. Funding level: $96,800.

Project description: The objectives of this project are to develop microwave exposure systems for biological material which have well-defined, uniform field characteristics, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave field in a small laboratory space. At present, it is difficult to accurately measure low-level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermistor and thermocouple detectors, chemical reactions, liquid crystals, and photographic film are some of the techniques which will be investigated.

Nonionizing Radiation (microwaves)—Project N2–74

Project title: "Effects of 2450 MHz CW Microwave Radiation on the Embryonic Development of Japanese Quail."

Studies to determine human health effects.

Total man-years: 1.2. Funding level: $52,800.

Project description: The objectives of this project are to determine the effects of 2450 MHz CW microwave radiation on the embryological development of Japanese quail. Fertilized Japanese quail eggs were exposed to 2450 MHz microwave radiation for four hours per day during the first five days of incubation. A power level ($30 mW/cm^2$) was chosen that would hold the temperature of the eggs at incubation temperature (35–37°C). The newly hatched quail were examined for changes in percent hatched, gross deformaties and several blood parameters. The blood parameters studied were hermatric hemoglobin, erythrocyte number and differential leucocyte percentages.

Non-ionizing radiation (microwaves)—Project N3–74

Project title: "Effects of 2450 MHz Microwave Radiation on Biological Material at Cellular and Macromolecular Level."

Studies to determine human health effects.

Total man-years: 0.8. Funding level: $35,200.

Project description: The objectives of this project are to determine how 2450 MHz microwave radiation interacts with biological material at the cellular and a macromolecular level, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Several strains of bacteria, one bacteriophage and solutions of DNA have been exposed to 2450 MHz microwaves at power levels sufficient to maintain a temperature of 37° C. Bacterial growth rate curves and bacteriophage lysis times have been compared in exposed and control situations. Thermal denaturation curves of control and exposed DNA solutions have been compared with the aid of an ultraviolet spectrophotometer equipped with a temperature programmer. Embryos from mice were exposed for 22 hours in test tubes at $100 mW/cm^2$ during the 2 to 4 cell stage and implanted in other mice for continued development. Washed rabbit erythrocytes have been exposed at several power levels and the cells examined for leakage of potassium and hemoglobin and changes in osmotic resistance.

Nonionizing Radiation (microwaves)—Project N4–74

Project title: "Effects of Microwave Radiation on the Neural Response."

Studies to determine human health effects.

Total man-years: 1.25. Funding level: $55,000.

Project description: The objective of this project is to determine the effects of microwave radiation on the functioning of the central nervous system when exposed to CW and modulated microwave radiation in the frequency range of 1–10 GHz. Isolated neurons such as the adominal ganglion of the *Aplysia*, the sciatic nerve of the frog, and the saphenous nerve of cats will be exposed to CW and modulated microwave radiation in the power density range of 1–10 mW/cm^2. The effects of the radiation on cell membrane potentials, action potential and conduction velocity will be investigated. More complex systems such as the exposed spinal cord of decerebrated cats will be exposed. These test systems will be used to investigate the effects of radiation on synaptic neurotransmitters.

Nonionizing Radiation (microwaves)—Project N5–74

Project title: "Development of Microwave Instrumentation." (Contract—Duke University.)

Studies to determine human health effects.

Funding level: $15,267.

Project description: The proposed work of this contract is threefold: (1) Study the electrical dipole model of the neural membrane and its implications, and to determine the unknown parameters in the interaction of the dipole model with microwave radiation; (2) Develop microwave instrumentation and methods to investigate microwave-neuron interactions over the 0.2 to 3 GHz frequency band; and (3) Develop the instrumentation and dosimetry of a more accurate method of determining the microwave power absorbed by a neuron.

PROJECT DESCRIPTIONS—FISCAL YEAR 1975

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–75

Project title: "Theoretical Basis of Dose-Response Relationships."

Studies to determine human health effects.

Total man-years: 2.5. Funding level: $110,000.

Project description: The objective of this project is to develop a mathematical-theoretical model of the effects of ionizing radiation at the cellular level. Experimental and theoretical approaches are being developed. Experimental systems incorporating spectrometry systems have designed to facilitate the delivery of measured doses of alpha, beta or gamma radiation to cell cultures. A theoretical treatment, built upon data from the literature, can be used to focus the experimental work and to predict the nature of dose-response relationships under low-dose, low-dose rate conditions.

Ionizing Radiation—Project I2–75

Project title: "Study of the Combined Effects of Smoking and Inhalation of Uranium Ore Dust, Radon Daughters and Diesel Oil Exhaust Fumes in Hamsters and Dogs." (Contract—Battelle Northwest-Pacific Northwest Laboratory.)

Study to determine the human health effects.

Funding level: $200,000.

Project description: As a major part of an integrated research program on the effects of exposure to radon and daughters on the development of lung cancer in uranium miners, the following animal studies were initiated:

1. Groups of hamsters were exposed to the following combinations: (*a*) Radon daughters on room air nuclei; (*b*) Radon daughters and carnotite ore dust; (*c*) Diesel engine exhaust alone; (*d*) Diesel exhaust fumes, radon daughters and ore dust; and (*e*) Carnotite ore dust.

Concentrations of radon and daughters, composition of ore dust and concentrations of other toxic agents in the diesel oil exhaust fumes were carefully controlled. After being exposed to predetermined cumulative dosage levels, the animals were maintained for life for the observation of pathological changes, particularly lung cancer and emphysema.

2. To test specifically the possible synergistic effects of radon and daughters and cigarette smoking studies were initiated on three groups of 18 dogs as described below:

a. Dogs exposed to radon and daughters on carnotite ore—exposure for 4 hours per day, 7 days per week at concentrations of 15 nanocuries per liter; with sham smoking;

b. Dogs exposed to radon plus daughters on ore as in (a), plus two working shifts of smoking (total of 10 cigarettes per day wtih resting on alternate hours);

Regular clinical, radiological and radiographic examinations will be made during and after smoking and radon exposures. The dogs, except for one in each group which will be sacrificed for early histopathological studies, will be held for their remaining life span with observations of pulmonary changes and lung cancer as the end point.

Nonionizing Radiation (microwaves)—Project N1–75

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years :0.80. Funding level: $35,200.

Project description: The objectives of this project are to develop microwave exposure systems for biological material which have well-defined, uniform field characteristics, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of microwaves was completed. Based on these studies, a set of specifications was written for a microwave field in a small laboratory space. At present, it is difficult to accurately measure low-level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermistor and thermocouple detectors, chemical reactions, liquid crystals, and infrared microscopes are some of the techniques which will be investigated. Other instruments for measuring incident and absorbed energy will be evaluated as they become available.

Nonionizing Radiation (microwaves)—Project N2–75

Project title: "Measurement of Energy Absorption from Microwave Fields."

Studies to determine human health effects.

Total man-years: 1.2. Funding level: $52,800,

Project description: Measurement of the absorption of microwave energy on the basis of fundamental physical laws. Microwaves are absorbed in a spherical shell of dielectric material enclosing a dry gas or a spherical shell of dry gas enclosing the dielectric. Temperature changes of the dielectric are transmitted to the gas which expands in accord with the ideal gas law over the range of pressure and temperatures encountered.

Nonionizing Radiation (microwaves)—Project N3–75

Project title: "Effects of 2450 MHz CW Microwave Radiation on the Embryonic Development of Japanese Quail."

Studies to determine human health effects.

Total man-years: 1.5. Funding level: $66,000.

Project description: The objectives of this project are to determine the effects of 2450 MHz CW microwave radiation on the embryological development of Japanese quail. Fertilized Japanese quail eggs were exposed to 2450 MHz microwave radiation at various times and durations during the incubation period. Temperature and humidity conditions are carefully controlled and may be varied to suit the experimental protocol. The newly hatched quail are examined for changes in percent hatched, gross deformities and several blood parameters. The blood parameters studied were hematocrit, hemoglobin, erythrocyte and leukocytes number and differential leukocyte percentages.

Nonionizing Radiation (microwaves)—Project N4–75

Project tile: "Effects of 2,450 MHz Microwave Radiation on Biological Materials at Cellular Level."

Studies to determine human health effects.

Total man-years: 1.1. Funding level: $48,400.

Project description: The objectives of this project are to determine how 2,450 MHz microwave radiation interacts with biological material at the cellular and macromolecular level, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Various cellular and macromolecular systems are exposed to microwave radiation at carefully controlled temperatures and exposure levels. Much of the work has been at 37°C. Some biological systems employed in the study are: bacteria and bacteriophage, solutions of DNA, 2–4 cell stage embryos from mice, rabbit erythrocytes and human mouse lymphocytes.

Nonionizing Radiation (microwaves)—Project N5–75

Project title: "Effects of Microwave Radiation on the Neural Response."

Studies to determine human health effects.

Total man-years: 0.25. Funding level: $11,000.

Project description: The objective of this project is to determine the effects of microwave radiation on the functioning of the central nervous system when exposed to CW and modulated microwave radiation in the frequency range of 1–10 GHz. Isolated neurons such as the adominal ganglion of the *Aplysia*, the sciatic nerve of the frog, and the saphenous nerve of cats will be exposed to CW and modulated microwave radiation in the power density range of 1–10 mW/cm^2. The effects of the radiation on cell membrane potentials, action potential and conduction velocity will be investigated. More complex systems such as the exposed spinal cord of decerebrated cats will be exposed. These test systems will be used to investigate the effects of radiation on synaptic neurotransmitters.

Nonionizing Radiation (microwaves)—Project N6–75

Project title: "Development of Microwave Instrumentation." (Contract—Duke University.)

Studies to determine human health effects.

Funding level: $15,267.

Project description: The proposed work of this contract is threefold: (1) Study the electrical dipole model of the neural membrane and its implications, and to determine the unknown parameters in the interaction of the dipole model with microwave radiation; (2) Develop microwave instrumentation and methods to investigate microwave-neuron interactions over the 0.2 to 3.0 GHz frequency band; and (3) Develop the instrumentation and dosimetry of a more accurate method of determining the microwave power absorbed by a neuron.

PROJECT DESCRIPTIONS—FISCAL YEAR 1976

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–76

Project title: "Theoretical Basis of Dose-Response Relationships."

Studies to determine human health effects.

Total man-years: 2.9. Funding level: $127,600.

Project description: The objective is to examine whether generalized conceptual schemes can be proposed within which experimental and theoretical work can be directed to answer critical questions in dose-response analysis. This project has included the development of a generalized theoretical model for the effects of ionizing radiation at the cellular level. A three-state model at the cellular level (normal cells, killed cells, altered cells) appears to encompass existing data and existing models on the effects of ionizing radiation. Such a model can be used to focus experimental work which, in turn, will lead to further model development. Questions to be addressed are: (1) Whether, and at what level, models can incorporate effects of chemical, biological and physical agents;

(2) whether paradigms for extrapolation can be proposed; and (3) whether correspondence rules can be mechanistic (relate microevents to macroevents) or only phenomenological (macroevents only).

Nonionizing Radiation (microwaves)—Project N1–76

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years: 0.9. Funding level: $39,600.

Project description: The objectives of this project are to develop microwave exposure systems for biological material which have well-defined, uniform field characteristics, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of and techniques for exposing biological specimens have been completed. Based on these studies, exposure systems will be designed and developed which provide known electromagnetic field characteristics. At present, it is difficult to accurately measure low level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermistor and thermocouple detectors, chemical reactions, liquid crystals and photographic film are some of the techniques which will be investigated. Other techniques to determine energy absorption will be evaluated as they become available.

Nonionizing Radiation (microwaves)—Project N2–76

Project title: "Investigation of Microwave Radiation Effects on Neurological Functioning."

Studies to determine human health effects.

Total man-years: 0.5. Funding level: $22,000.

Project description: The objective of this project is to determine the effects of microwave radiation on the functioning of the central nervous system when exposed to CW and modulated microwave radiation in the frequency range of 1–10 GHz. Isolated neurons such as the abdominal ganglion of the *Aplysia*, the sciatic nerve of the frog, and the saphenous nerve of cats will be exposed to CW and modulated microwave radiation on cell membrane potentials, action potentials and conduction velocity will be investigated. More complex systems such as the exposed spinal cord of decerebrated cats will be exposed. These test systems will be used to investigate the effects of radiation on synaptic neurotransmitters.

Nonionizing Radiation (microwaves)—Project N3–76

Project title: "Effects of 2450 MHz Microwaves on Embryonic Development of Japanese Quail."

Studies to determine human health effects.

Total man-years: 1.3. Funding level: $57,200.

Project description: The objectives of this project are to determine the effects of 2450 MHz CW microwave radiation on the embryological development of Japanese quail and the subsequent growth, reproduction, and immunological response of the mature quail which had been exposed during the developmental period. Fertilized Japanese quail eggs were exposed to 2450 MHz CW microwave for various periods of embryonic development at power densities of 30 mW/cm^2 and 5 mW/cm^2. The effects of exposure on hatchability, gross deformities and hematological parameters were measured in the 2 day old quail. Fertilized eggs were also exposed to 5 mW/cm^2 for the first 12 days of development. The quail were kept to maturity and growth rates, egg production, fertility and immunological response were measured.

Nonionizing Radiation (microwaves)—Project N4–76

Project title: "Effects of 2450 MHz Microwave Radiation on Biological Materials at Cellular Level."

Studies to determine human health effects.

Total man-years: 1. Funding level: $44,000.

Project description: The objectives of this project are to determine how 2450 MHz microwave radiation interacts with biological material at the cellular and macromolecular level, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Various cellular and macromolecular systems are exposed to microwave radiation at carefully controlled temperatures and exposure levels. Much of the work has been at 37°C. Biological systems employed in the study are: bacteria and bacteriophage, solutions of DNA, 2–4 cell stage embryos from mice, rabbit erythrocytes and rat lymphocytes.

Nonionizing Radiation (Extra Low Frequency)—Project N5–76

Project title: "Effects of 60 Hz Fields on the Mammalian Central Nervous System." (Contract—University of California—Los Angeles.)

Studies to determines the human health effects.

Funding level: $99,994.

Project description: The objectives of this research are to determine the effects of 60 Hz fields from high voltage transmission lines on the central nervous system of mammals. Environmental field conditions similar to those found in the vicinity of high voltage transmission lines will be simulated. These field gradiants will range from 1 to 2000 volts/meter. The effects of these fields on the biological rhythms in rats and conditional behavior in monkeys will be evaluated. The effects on the neuroendocrine mechanism in rats and primates will be examined by using 17-hydroxysteroids, calcium, phosphorus, vanilmandelic acid and other urinary indicators of biorhythmicity. Changes in the neurochemistry of brain tissue of cats will be studied. These studies will include the measurement of both Ca and amino acid effluxes from the cerebral cortex of the cat.

PROJECT DESCRIPTIONS—FISCAL YEAR 1977

IONIZING AND NONIONIZING RADIATION

In-house and Contracts

Ionizing Radiation—Project I1–77

Project title: "Theoretical Basis of Dose Response Relationships."

Study to determine human health effects.

Total man-years: 0.2. Funding level: $880,000.

Project description: The purpose of this project is to continue development of theoretical models of dose-response relationships for ionizing radiation at the cellular level and to begin the development of generalized conceptual schemes encompassing chemical, biological and physical agents. The current approach is to: (1) Accumulate existing data for chemical, biological and physical agents on cell survival, mutagensis and carcinogenesis that is suitable for dose-response analysis; (2) selection of models that can be applied to the data base in (1); and (3) propose conceptual schemes within which further data can be accumulated to answer critical questions raised in (1) and (2).

Nonionizing Radiation (Microwaves)—Project N1–77

Project title: "Microwave Exposure System and Microwave Dosimetry."

Studies to determine human health effects.

Total man-years: 1.1. Funding level: $48,400.

Project description: The objectives of this project are to develop microwave exposure systems for biological material which have well-defined, field characteristics, and to develop dosimetric relationships for energy absorption. A thorough study of the research requirements on the biological effects of and techniques for exposing biological specimens have been completed. Based on these studies, exposure systems will be designed and developed which provide known electromagnetic field characteristics. At present, it is difficult to accurately measure low level microwave fields and to determine the mechanisms by which the fields interact with matter. It is necessary, therefore, to conduct dosimetric studies so as to develop analytical interaction models. Microcalorimetry, thermistor and thermocouple detectors, and liquid crystals are some of the techniques which will be investigated. Other techniques to determine energy absorption will be evaluated as they become available.

Nonionizing Radiation (Microwaves)—Project N2–77

Project title: "Effects of Microwaves on Neural Response."

Study to determine human health effects.

Total man-years: 0.8. Funding level: $35,200.

Project description: The objective of this project is to determine the effect of microwave radiation on neurological response. Isolated neurons such as the abdominal ganglion of the *Aplysia*, the sciatic nerves of frogs and the saphenous nerves of cats will be exposed to CW, pulsed and modulated microwave radiation in the power density range of 1–10 mW/cm^2. The effects of the microwave radiation on the strength-duration of a stimulus to produce an action potential, amplitude of the response, and conduction velocity will be investigated. The fatigue and recovery of the neurons under rapid, multiple stimulation will also be studied.

Nonionizing Radiation (microwaves)—Project N3–77

Project title: "Effects of 2450 MHz Microwave Radiation on Biological Materials at Cellular Level."

Studies to determine human health effects.

Total man-years: 1. Funding level: $44,000.

Project description: The objectives of this project are to determine how 2450 MHz microwave radiation interacts with biological material at the cellular and macromolecular level, to observe any effects of this interaction and to relate the amount of microwave energy absorbed to the effects. Biological systems employed in the study are: bacteria and bacteriophage, solutions of DNA, 2–4 cell stage embryos from mice, rabbit erythrocytes and rat lymphocytes. In these experiments, the temperature, humidity, and other various growth conditions have been carefully monitored in order to eliminate any effects not intrinsically caused by the microwave radiation.

Nonionizing Radiation (microwaves)—Project N4–77

Project title: "Effects of 2450 MHz Microwaves on Embryonic Development, Immunology and Fertility."

Study to determine human health effects.

Total man-years: 1.3. Funding level: $37,200.

Project description: The objectives of this project are to determine the effects of 2450 MHz CW microwave radiation on the embryological development of Japanese quail and the subsequent growth, reproduction, and immunological response of the mature quail which had been exposed during the developmental period. Fertilized Japanese quail eggs were exposed to 2450 MHz CW microwave for various periods of embryonic development at power densities of 30 mW/cm^2 and 5 mW/cm^2. The effects of exposure on hatchability, gross deformities and hematological parameters were measured in the 2 day old quail. Fertilized eggs were also exposed to 5 mW/cm^2 for the first 12 days of development. The quail were kept to maturity and growth, rates, egg production, fertility and immunological reponse were measured.

Nonionizing Radiation (microwaves)—Project N5–77

Project title: "Effects of Microwave Radiation on the Nervous System." (Contract—University of Washington.)

Study to determine human health effects.

Funding level: $129,867.

Project description: The objective of this project is to determine the effects of long-term, low-level, exposure to 918 and 2450 MHz microwave radiation on the central nervous system and behavior. Long-evans male rats, 80–90 days of age will be exposed to 915 and 2450 MHz circular polarized microwave radiation at a power density level such that the specified absorption rate will be equivalent to that produced in a 5 mW/cm^2 plane wave field. The exposure will be 8 hours a day, 7 days a week for 4 months. Two months postirradiation evaluations will be performed. Rats will also be exposed to 2450 MHz plane wave microwave field at a power density of 500 μW/cm^2 using the same schedule as that stated above. The following indicators of biological effects will be made:

1. Biochemistry—Serum content for sodium, calcium, phosphorus, PTH, SH groups and cholorinesterase activity of the blood and 17-ketosteroids in urine will be measured.
2. Behavior—Animals will be evaluated for free-operant and free-repertoire behavior. Animals will be observed in the irradiation chambers and their specific orientation to the field, sleep, grooming, sniffing, rearing, drinking, eating, etc., will be recorded.

3. Electroencephalography—EEG recordings will be made on the animals following the 4-month irradiation period.

In addition to the above endpoints, some behavioral teratology, cataract evaluation, and longevity data will be obtained.

Nonionizing Radiation (microwaves)—Project N6–77

Project title: "Effects of Microwave Radiation on the Nervous System." (Contract—University of Utah.)

Study to determine human health effects.

Funding level: $98,194.

Project description: The objective of this period is to determine the effects of long-term, low-level exposure to 915 and 2450 MHz microwave radiation on the central nervous system and behavior. Long Evans male rats will be exposed to a CW plane wave microwave field at frequencies of 915 to 2450 MHz and power density of 5 mW/cm^2. The animals will be exposed for 8 hours a day, 5 days a week for 16 weeks. An eight week recovery period will follow the exposure period. The following measurements will be made:

1. Biochemistry—Biochemical analysis of the cholinesterase activity of the blood, the SH group in the blood, and ketosteroids in the urine will be measured.
2. Behavior—Rodent activity will be measured using a rodent activity wheel. Water and food intake will be measured. Rats will be trained to lever press for food reward on a FR–DRL multiple schedule. Total response and reinforcement for each schedule component as well as response during time out between each component will be recorded.
3. EEG—EEG will be recorded biweekly using epidural removable stainless steel electrodes. These recordings will be made while the microwave radiation is turned off.

Nonionizing Radiation (Extra Low Frequency)—Project N7–77

Project title: "Effects of 60 Hz Fields on the Mammalian Central Nervous System." (Contract—University of California-Los Angeles.)

Studies to determine the human health effects.

Funding level: $99,994.

Project description: The objectives of this research are to determine the effects of 60 Hz fields from high voltage transmission lines on the central nervous system of mammals. Environmental field conditions similar to those found in the vicinity of high voltage transmission lines will be simulated. These field gradients will range from 1 to 2000 volts/meter. The effects of these fields on the biological rhythms in rats will be evaluated. The effects on the neuroendocrine mechanism in rats and primates will be examined by using 17-hydroxysteriods, calcium, phosphorus, vanilmandelic acid and other urinary indicators of biorhythmicity. Changes in the neurochemistry of brain tissue of cats will be studied. These studies will include the measurement of both Ca^{2+} and amino acid effluxes from the cerebral cortex of the cat.

PROJECT DESCRIPTIONS—FISCAL YEAR 1978

NONIONIZING RADIATION

In-house and Contracts

Nonionizing Radiation—Proposed 1978

1. Project title: "Effects of Microwave Radiation on Neural Response." Total man-years: 1.8. Funding level: $79,200.
2. Project title: "Effects of 2450 MHz CW and Pulsed Microwave Radiation on Embryonic Development, Immunology and Fertility." Total man-years: 1.5. Funding level: $66,000.
3. Project title: "Effects of Microwave Radiation on Biological Membrances." Total man-years: 1. Funding level: $44,000.
4. Project title: "Effects of Microwaves on the Nervous System." (Contract University of Washington.) Funding level: $75,000.
5. Project title: "Effects of Microwaves on the Nervous System." (Contract University of Utah.) Funding level: $75,000.
6. Project title: "Effects of 60 Hz Fields on the Mammalian Central Nervous System." (Contract—University of California-Los Angeles.) Funding level: $100,000.

PROJECT DESCRIPTIONS—IONIZING RADIATION

EXTRAMURAL RESEARCH

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

RESEARCH OBJECTIVES

LEAVE BLANK
PROJECT NUMBER
ES-01120

NAME AND ADDRESS OF APPLICANT ORGANIZATION
New York University Medical Center
550 First Avenue
New York, N.Y. 10016

NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Bernard S. Pasternack 064-26-0891, Assoc. Professor, Dept. of Environmental Medicine

Naomi H. Harley 124-26-4135, Assoc. Res. Scientist, Dept. of Environmental Medicine

TITLE OF PROJECT
Human Radioactivity Dose Study

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS. UNDERSCORE THE KEY WORD (NOT TO EXCEED 10) IN YOUR ABSTRACT.

Abstract - The purpose of this study is to provide detailed dose estimates to the critica cells in tumor formation from the important radionuclides expected to be prevalent in our environment within the next decade. Two groups of nuclides are to be studied, the alpha emitters which predominate in spent nuclear fuel, namely ^{238}Pu, ^{241}Pu, ^{241}Am, ^{242}Cm ^{244}Cm and the beta emitting fission product ^{85}Kr. Estimates are that by 1985 4×10^9 Curies of the transuranics will be reprocessed per year, while atmospheric ^{85}Kr levels could be as high as 10^4 pCi/m^3 by the turn of the century.

Release of transuranics to the environment can result in human exposures by ingestio or inhalation. Soluble forms of these nuclides are bone seekers and critical cells on bone surfaces are irradiated. Inhalation of less soluble particulates irradiates critical cells in the lower lung over long time intervals. Krypton-85 is very soluble in body fat and 13% of body storage fat is located in yellow bone marrow in bone shafts. It is thus capable of producing an important beta dose to bone cells adjacent to bone marrow as well as a dose to critical basal cells in bronchial epithelium upon inhalation.

There is no human experience with high levels of these emitters to indicate their absolute toxicity. Whether the exposure is from inhaled or ingested material, the distribution of the transuranic nuclides in the body is quite different from that of radium or radon daughter exposure where human data on tumor induction in bone and lung do exist. A key to evaluating the toxicity of these nuclides as well as ^{85}Kr lies in the estimation of the critical cell rad doses for their disposition in the body and compariso of this dose with those estimated where tumor induction in humans has occurred. In this proposal we show that this type of detailed dose estimate is now possible.

All of our dose estimates will be computed from measured energy loss data in tissue-like material. The measurement of beta energy loss will allow unique calculations since these data are not as yet available for accurate spatial dosimetry.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

RESEARCH OBJECTIVES

LEAVE BLANK
PROJECT NUMBER
ES - 01207

NAME AND ADDRESS OF APPLICANT ORGANIZATION

Albany Medical College, 47 New Scotland Avenue, Albany, N.Y., 12208

NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Ernest B. Hook	203-28-9873	Associate Professor	Dept. of Pediatrics, Alb. Med. Colleg
Matthew Rogan	061-36-4146	Acting Director, Newborn Nursery, Dept. of Pediatrics, Alb. Med. Coll.	
Norma Hatcher	130-44-0075	Research Associate	Dept. of Pediatrics, Alb. Med. Colleg
Lydia Abad	118-42-6116	Director of Neonatology	St. Peters Hospital

TITLE OF PROJECT

Environmental Factors Related to Chromosome Damage

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS. UNDERSCORE THE KEY WORD (NOT TO EXCEED 10) IN YOUR ABSTRACT.

The goals of this study are 1) to determine what environmental factors are associated with "somatic mutations" as manifested in chromosome breakage and other evidence of chromosome damage which occurs in those with evidence of embryotoxicity and 2) to investigate the feasibility of a new method of evaluation of chromatid interchanges (using Hoechst 33258 binding) and its applicability to the determination of chromosome damage in the population under study; and, in so doing, to assess the more general applicability of this approach to the monitoring of populations "at risk" which are known to be exposed to possible environmental hazards such as X-irradiation, pesticides, etc. Chromatid interchanges as detected with this method will be correlated with the frequency of chromosome breakage in the population under study as well as with history of exposure to radiation, among other factors.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

RESEARCH OBJECTIVES

LEAVE BLANK
PROJECT NUMBER
ES-01536

NAME AND ADDRESS OF APPLICANT ORGANIZATION

University of Oregon, Eugene, Oregon 97403

NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Novitski, Edward	Professor of Biology	545-44-4509

TITLE OF PROJECT The Nature of Radiation Induced Genetic Damage

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS. UNDERSCORE THE KEY WORD (NOT TO EXCEED 10) IN YOUR ABSTRACT.

The relation between radiation-induced mutations and chromosome breaks is not understood at the present time; a new hypothesis of the whole animal from only one of the first two cleavage products appears to resolve some of the problems. The research will focus on the study of the production of mosaics in Drosophila melanogaster as a function both of X-ray dose and chemical treatment, and the computer analysis of genetic data on chromosome loss and dominant lethal production in view of this hypothesis.

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NIH 393 (FORMERLY PHS 398)
Rev. 1/73

PAGE 2

TABLE II

GRANT NO. ES00002-14

NARRATIVE JUSTIFICATION OF FUNDS REQUESTED FOR RADIOBIOLOGY

PROGRAM:

The overall aim of this program is to learn more about the biologic effects of ionizing radiation, including particulary the effects of of alpha radiation in the lungs and the possible interactions of alpha-emitters and chemical carcinogens in malignant transformation and the production of lung tumors.

EQUIPMENT:

Walk-in Environmental Chamber

A cold room is needed for two reasons: First, the increased demand for tissue culture media has created an acute cold storage problem. Since media is prepared in bulk and must be stored 48 hours until sterility tests are completed, up to 100 liters must be stored in isolation at one time. The second reason is our work is leading toward enzymatic studies in which chromatography at 4°C is necessary. This will require at least a 6' x 6' cold area. The two requirements together make the acquisition of a cold room very important to our research program.

[illegible]
Not for publication or publication reference.

U. S. Department of
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NOTICE OF RESEARCH PROJECT

PROJECT NO. DO NOT USE THIS SPACE

TITLE OF PROJECT

QUANTITATIVE GENETIC STUDY OF ENVIRONMENTAL MUTAGENS

GIVE NAMES, DEPARTMENTS, AND OFFICIAL TITLES OF PRINCIPAL INVESTIGATORS OR PROJECT DIRECTORS AND ALL OTHER PROFESSIONAL PERSONNEL ENGAGED ON THE PROJECT.

William R. Lee, Principal Investigator, Professor of Zoology

Charles S. Aaron, Research Associate

NAME AND ADDRESS OF APPLICANT INSTITUTION

Louisiana State University and Agricultural and Mechanical College, Baton Rouge, La. 7

SUMMARY OF PROPOSED WORK – *(200 words or less – Omit Confidential data.)*

In the Science Information Exchange summaries of work in progress are exchanged with government and private agencies supporting research in the biosciences and are forwarded to investigators who request such information. Your summary is to be used for these purposes.

To evaluate the genetic hazard of chemicals in our environment and understar their mode of action it is necessary to place chemical mutagenesis on a quantitat basis in a eukaryote organism that can be thoroughly and economically analyzed genetically. Ethyl methanesulfonate (EMS) was selected as the mutagen for developing a model test system because of its known mutagenic effectiveness and i simple chemical structure which makes it relatively easy to synthesize with radionuclides having high specific activity. The mutagenic action of EMS is cons due to its alkylation of DNA, a point of view supported by previous work on this project using Drosophila in a bio-assay of blood plasma from hamsters that had be previously injected with EMS. To place the dosage of EMS on a quantitative basis alkylation of DNA in *Drosophila melanogaster* spermatozoa is measured on a per spe cell basis and then further divided into alkylation at specific sites such as th 7 position of guanine. This dosimetry will then permit the construction of dosag response curves with the dose in terms of alkylation and the response in terms of extensive mutational spectrum developed with Drosophila. This project differs fr previous work with alkylation in that we are studying both alkylation and the gene consequence within the same germinal tissue of a eukaryote. Results of these test would eventually enable us to determine whether, as the dose is reduced, repair mechanisms become sufficiently effective to reduce the mutational effect to no gre than the spontaneous rate or if there is a genetic hazard due to low level exposur to alkylating agents. This answer is basic to determining the genetic hazard of a constant low level mutagen in our environment. This work is being expanded to include the bisulfite ion, heavy metals and other environmental mutagens.

PROFESSIONAL SCHOOL *(medical, dental, etc.)* WITH WHICH THIS PROJECT SHOULD BE IDENTIFIED	SIGNATURE OF PRINCIPAL INVESTIGATOR	DATE
Graduate School	William R. Lee William R. Lee	April 25,

DO NOT WRITE BELOW THIS LINE – FOR OFFICE USE ONLY

SUPPORTING AGENCY

METHOD OF SUPPORT *(Check one)*

☐ Agency Staff (Intramural) ☐ Negotiated Contract ☐ Special Project Grant ☐ Research Grant ☐ Other (Specify)

FUNDS OBLIGATED CURRENT F.Y.	NUMBER OF FUTURE YEARS TENTATIVELY ASSURED BEYOND CURRENT FISCAL YEAR	BEGINNING DATE	ESTIMATED COMPLETION DAT

Prepared for the Science Information Exchange.
Not for publication or publication reference.

HEALTH, [illegible]
PUBLIC HEALTH SERVICE
NOTICE OF RESEARCH PROJECT

ES-00238

Submit with completed Application to: Division of Research Grants, National Institutes of Health, Bethesda 14, Md.

TITLE OF PROJECT:

Effects of X-Irradiation on Insecticide Toxicity

Give names, departments, and official titles of PRINCIPAL INVESTIGATORS or PROJECT DIRECTORS and ALL OTHER PROFESSIONAL PERSONNEL engaged on the project. Include day-month-year of birth of principal investigators.

George W. Ware, Jr., 432-28-0954 August 27, 1927
Professor of Entomology
Department of Entomology

NAME AND ADDRESS OF APPLICANT INSTITUTION:

University of Arizona
Tucson, Arizona 85721

SUMMARY OF PROPOSED WORK — (200 words or less — Omit Confidential data.)

In the Science Information Exchange summaries of work in progress are exchanged with government and private agencies supporting research in the bio-sciences and are forwarded to investigators who request such information. Your summary is to be used for these purposes.

Previous research by the principal investigator has produced surprising results when X-irradiated insects were treated with insecticides. It is the purpose of this project to irradiate all stages of insect development at varying intervals and dosages before and after exposure to varying dosages of insecticides, and to determine the effects on their toxicity to these different stages. From these time, toxicant, and irradiation dosage variations the modes of toxic action will be explored more intricately through physiological studies. These will involve looking for cholinesterase and aliesterase changes, amino acid alterations, peroxide, fatty acid and free cation levels, both with regard to changes in the insect biochemistry resulting from the toxicant and irradiation.

Aside from the purely physiological aspects, we will also look for changes in development rate, body weight, general activity or behavior, feeding rates and longevity, all to be compared with the two control sets.

SIGNATURE OF PRINCIPAL INVESTIGATOR or PROJECT DIRECTOR George W. Ware, Jr.

Identify the Professional School (medical, dental, public health, graduate, or other) with which this project should be identified:

SCHOOL

INVESTIGATOR — DO NOT USE THIS SPACE

PHS, 166
REV. 12-61

FORM APPROVED
BUDGET BUREAU NO. 105-R002.

SECTION 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

RESEARCH OBJECTIVES

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PROJECT NUMBER

NAME AND ADDRESS OF APPLICANT ORGANIZATION

New York University Medical Center
550 First Avenue, New York, New York 10016

NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Norton Nelson, S.S. #089-26-4649, Professor and Chairman, Environmental M
Roy E. Albert, S.S. #096-28-5595, Professor, Environmental Medicine
Merril Eisenbud, S.S. #163-05-2581, Professor, Environmental Medicine
Edward D. Palmes, S.S. #229-12-4053, Professor, Environmental Medicine

See pages 10-29 for rest of professional personnel.

TITLE OF PROJECT

Research in the Environmental Health Sciences

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS. UNDERSCORE THE KEY WOR (NOT TO EXCEED 10) IN YOUR ABSTRACT.

This grant provides core support for a broad program in the environmental health sciences. The research under way and proposed is broadly relevant to adverse health effects from environmental factors. The general objectives of the research are to define the nature and extent of such effects with the aim of instituting appropriate preventive or control procedures where required. Interests range from acute to chronic health effects including, in the latter, cancer and the degenerative diseases.

The research encompasses laboratory studies on the biochemical mode of action of environmental toxicants, exploratory studies aimed at improving the reliability and efficiency of predictive toxicological test improvement of diagnostic procedures for diseases possibly related to environmental factors, epidemiological investigations and field studies on the distribution of pollutants.

See page 30 for Table of Contents for Research Plan.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

RESEARCH OBJECTIVES

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PROJECT NUMBER	ES-00831

NAME AND ADDRESS OF APPLICANT ORGANIZATION

Wright State University Research Institute, Inc.
Colonel Glenn Highway, Dayton, Ohio 45431

NAME, SOCIAL SECURITY NUMBER, OFFICIAL TITLE, AND DEPARTMENT OF ALL PROFESSIONAL PERSONNEL ENGAGED ON PROJECT, BEGINNING WITH PRINCIPAL INVESTIGATOR

Charles Colbert, 293-22-9223, Director, Radiological Research Laborato
Hendrik van Hulst, 296-54-5119, Research Associate, Radiological Rsch.
Rudi Schroeer, 294-32-4143, Research Associate, Radiological Rsch. Lab
Ilse Tebbetts, 008-22-0488, Research Assistant, Radiological Rsch. Lab

TITLE OF PROJECT

Rapid Screening for Lead Poisoning

USE THIS SPACE TO ABSTRACT YOUR PROPOSED RESEARCH. OUTLINE OBJECTIVES AND METHODS. UNDERSCORE THE KEY (NOT TO EXCEED 10) IN YOUR ABSTRACT.

While the causes and cure of lead poisoning are well known, early tection before effects become irreversible remains one of two major stumbling blocks to eradication of this environmental disease. Diagno tests so far devised have limitations and there is need for a practica reliable and definitive test. We propose to determine whether our qua tative computer/scanner system for rapid screening of radiographs can effectively detect lead poisoning in its early stages. We also intend evaluate the usefulness of our system in measuring the extraction of l from bones during treatment. Because of our capability for objective measurement we should be able to detect lead deposits in bones even wh they are not visible in radiographs. Our computerized system is wholl independent of subjective visual evidence and largely independent of f taking and processing variables, thus overcoming the drawbacks of trad tional radiographic screening methods.

We intend to analyze some 300 radiographs of known lead-poisoning by two of our standard methods for determining skeletal status: (1) m surement of radiographic bone size, weight and density combined with comparison of findings to normal values; (2) line-scanning of selected to establish a mineral distribution profile which may pinpoint dense d posits in growing ends of bones. If, as we expect, definitive pattern emerge, we will test our screening capability in a blind study which w include 150 lead-poisoning cases and 150 normal subjects.

We will follow progress of 50 or more patients receiving treatment by testing for significant changes in skeletal status in accordance with standard procedures.

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National Institutes of Health,
Bethesda, Md., June 28, 1977.

Hon. Adlai E. Stevenson,
Chairman, Subcommittee on Science, Technology, and Space, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Senator Stevenson: This is in response to your and Senator Wendell H. Ford's letters of May 19, about Federal radiation research and regulatory programs, addressed to:

Dr. Donald S. Fredrickson, Director, National Institutes of Health
Dr. Guy R. Newell, Acting Director, National Cancer Institute (NCI)
Dr. Ruth L. Kirschstein, Director, National Institute of General Medical Sciences (NIGMS)
Dr. David P. Rall, Director, National Institute of Environmental Health Sciences (NIEHS)

Since the NCI, NIGMS, and NIEHS constitute three of the eleven component Institutes of the National Institutes of Health (NIH), we are submitting this single response for the entire agency.

The NIH is a research agency, and as such it both conducts research intramurally (by in-house staff) and supports research extramurally (through grants and contracts). We are *not* a regulatory agency but operate under the purview of various other agencies, such as the Nuclear Regulatory Commission (NRC). The NIH operates under a specific license of broad scope.

Safety aspects

1. Ionizing radiation.—The use of radioactive materials and other sources of ionizing radiation in the NIH intramural research program is under the careful regulation of the NIH Radiation Committee and the Radiation Safety Branch, Division of Research Services (DRS). [See Enclosure 1: NIH Radiation Safety Guide.]

It has been estimated that approximately 80 percent of the NIH intramural biomedical research effort is dependent, in varying degrees, upon the use of ionizing radiation for clinical or research purposes. The radiation safety program is responsible for over 3,000 scientists and support personnel who are working directly with radioactive materials or X-ray producing electronic products. Approximately 14,000 shipments of radioactive materials are received annually by NIH, with a total activity of 190 Curies, and a value of $2,500,000. This use has been increasing at a rate of approximately 15–20 percent over the past decade. In addition, there are over 150 X-ray producing devices under surveillance.

NIH radiation safety activities are planned to assure compliance with the applicable chapters of Part 10, Code of Federal Regulations, the conditions of the seven various licenses issued to NIH by the NRC, other applicable Federal regulations (FDA, DOT, EPA, OSHA, Postal Service, etc.), and all DHEW and NIH policies related to the safe and effective use of ionizing radiation. The Radiation Safety Branch, DRS, also provides a variety of essential health physics services, including: package receipt and delivery, radioactive waste disposal, license administration, instrument calibration and repair, bioassays, personnel exposure records, surveillance, training, effluent monitoring, and technical assistance, etc. The objective of the program is to provide assistance to the NIH intramural research scientist so as to maximize the benefits to be derived from the use of ionizing radiation in biomedical research, while concurrently reducing personnel exposures and releases of radioactive materials to unrestricted areas to the lowest levels reasonably achievable. The use of ionizing radiation as a tool for performing other studies should not be confused with primary radiation research. No primary ionizing radiation research or regulatory activities, in the context of this inquiry, are being conducted. Enclosure 2 provides data on your "Ionization Radiation" format for the NIH Radiation Safety Activities.

2. Non-ionizing radiation.—The Environmental Safety Branch (DRS) is responsible for monitoring and surveillance of intramural non-ionizing radiation activities. Approximately 0.2 man-years ($3,000–$4,000) has been devoted to this each year since 1968.

The NIH intramural research and support programs use a broad spectrum of non-ionizing radiation. The sources include lasers, microwave devices, ultraviolet lights, and ultrasonic devices. NIH employees are provided protection from the hazards of non-ionizing radiation through an ongoing monitoring and surveillance program that: Reviews source equipment purchase requisitions to insure that correct safety devices are a part of the equipment; monitors and interests and interprets new and existing standards and regulations for the use of non-ionizing sources; and surveys operating equipment to determine if safety equipment and procedures are functioning adequately.

Research

From the standpoint of research (as contrasted with service to assure safety), the NIH supports a very wide range of projects. Enclosure 3,[1] is a computer printout of extramural projects and intramural projects for fiscal year 1976 which will illustrate the broad scope encompassed by the terms "ionizing radiation" and "non-ionizing radiation" (and we have only queried the computer file for these as "primary" indexing terms).

While it is possible to secure similar extramural printouts for previous years, the abstracts of project descriptions are not available for fiscal year 1972 or earlier. It is not possible to obtain computerized retrieval of intramural projects for prior years.

In fiscal year 1976:

Ionizing radiation:	
1,483 Extramural projects	$122, 392, 501
49 Intramural projects	NA
Non-ionizing radiation:	
294 Extramural projects	17, 621, 200
29 Intramural projects	NA

Following are responses to two of your four specific questions:

Question 1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?"

Response. Changes in jurisdiction between 1968 and 1977, per se, have had little significant effect on NIH's overall effort in the radiation area. Specifically, the electronic product standards of the Bureau of Radiological Health, FDA, and the OSHA requirements have had very little impact. The NRC (formerly AEC) has had significant impact primarily as a result of continually increasing stringency of regulations in conjunction with the increased use of radioactive materials in biomedical research (166 percent increase at NIH since 1968). A very effective surveillance and compliance program is conducted by the NRC.

Question 2. Would you please describe the nature of the contracts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?"

Response. Although Maryland is an "agreement" State of the NRC, the nature of NIH's broad license is such that we deal directly with the NRC district office in King of Prussia, Pennsylvania. Contacts between NIH and various State groups in the radiation field are primarily referrals, consultations, license verification, and emergency preparedness.

There is little confusion concerning States' responsibilities, although they vary considerably from State to State; however, the responsibility of various Federal agencies such as NRC, EPA, DoT, ERDA, DoD, NBS, FDA, OSHA, U.S. Postal Service, etc., is a bit more obscure because of the large number involved, overlapping areas of interest, and the like.

Thank you for giving us this opportunity to provide comments on our radiation activities. We understand you will be hearing from the Department on questions 3 and 4. Please let us know if we can be of further assistance.

Sincerely yours,

DONALD S. FREDRICKSON, M.D.,
Director.

Enclosures.

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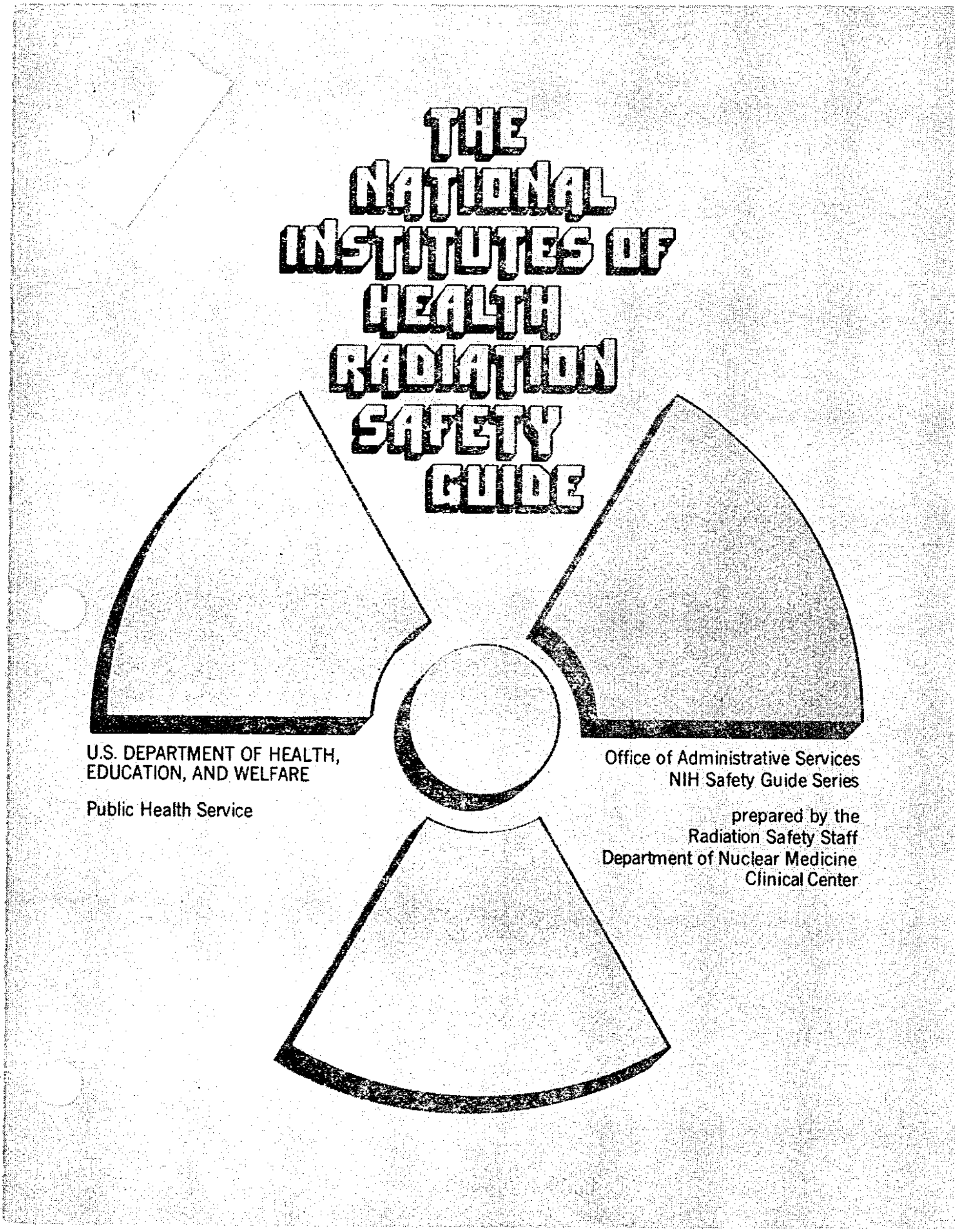
[1] The computer printout referred to has been retained in the committee files.

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develomt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain)	Other Studies (Explain) *
1968 In-House (Positions)												18 $250,000
1969 Extra-Mural (Funds) Total Funds												18 $295,000
1970												18 $320,000
1971												20 $335,000
1972												21 $365,000
1973												17 $370,000
1974												19 $422,000
1975												19 $539,000
1976												21 $667,000
1977												24 $928,000
Est. 1978												25 $1,187,000

applies to all years

*Radiation Sa activities (intramural). NIH Radiation Safety Guide: program philo and responsib ties.



THE NATIONAL INSTITUTES OF HEALTH RADIATION SAFETY GUIDE

U.S. DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Public Health Service

Office of Administrative Services
NIH Safety Guide Series

prepared by the
Radiation Safety Staff
Department of Nuclear Medicine
Clinical Center

Foreword

The 1972 edition of the NIH Radiation Safety Guide brings up to date the recommendations and requirements governing the use of radiation sources by the NIH Intramural Program.

NIH is using radionuclides in increasing quantities, under a specific license of broad scope issued by the U.S. Atomic Energy Commission. Possession of this license has greatly reduced the detailed problems of isotope procurement, but carries strict responsibilities governing use and ultimate disposal. NIH considers the AEC regulations as minimum requirements, and has broadened local controls to include radiation sources not under AEC surveillance.

Recommendations in the 1972 Guide have developed from years of experience in adapting general principles of radiation safety to the NIH environment. The procedures outlined in the Guide are designed to permit the maximum beneficial use of radiation sources with the minimum exposure to patients and personnel. Failure to follow the recommended procedures could result in a serious radiation overexposure, and a suspension or revocation of our license. All personnel using radiation sources are expected to become familiar with the NIH radiation safety requirements and to conduct their operations in accordance with them.

Robert Q. Marston, M.D.
Director,
National Institutes of Health

Introduction

The National Institutes of Health is authorized to procure and use radioactive materials on the Bethesda reservation under a "specific license of broad scope" issued by the Division of Materials Licensing of the Atomic Energy Commission. This license is contingent upon the existence of a Radiation Committee and a Radiation Safety organization which, among other requirements must:

1. Assure that any investigator using radioactive materials is qualified by training and experience, has the facilities to handle the materials safely, and proposes a use which is safe to all concerned.
2. Assure observance of all safety standards established by the Atomic Energy Commission, National Council on Radiation Protection and Measurements, and other regulatory or standards setting agencies.
3. Keep records of the receipt, storage, use, transfer, and ultimate disposal of all radioisotopes used at NIH.
4. Keep records of the monitoring of personnel and areas involved in the use of radionuclides and other sources of ionizing radiation.

NIH is subject to periodic inspection by the Division of Regulatory Operations of the Atomic Energy Commission to insure that all requirements of the license are being met. These inspections are very thorough, including monitoring checks of laboratory areas, inspection of procurement and disposition records, records of the qualifications of individual users, and records of administrations to patients. Violations of license requirements can result in a loss of the license.

All sources of ionizing radiation are not covered by the Atomic Energy Commission license. These sources are, however, controlled by regulations issued by the Director, NIH, upon recommendation of the Radiation Committee. Nonlicense sources include x-ray machines, high voltage accelerators, electron microscopes, and radioactive materials from sources other than reactor by-products.

This Guide describes rules and procedures required of NIH under the terms of AEC licensure, and for the use of non-licensed ionizing radiation sources as set forth by NIH regulations.

In total, the 1972 revision of the NIH Radiation Safety Guide represents several decades of intramural experience. Additionally, it reflects authoritative standards, guidelines, recommendations and research data concerning physical aspects and bioeffects of ionizing radiation obtained from the scientific literature.

The previous editions of this Guide included a reasonably comprehensive bibliography of the most important of these sources; the literature is now so extensive, however, that it is not feasible to include even a highly selective bibliography. Therefore, readers who desire documentation for any particular policy, procedure or quantitative data contained in these pages are invited to communicate directly with the NIH Radiation Safety office.

Although intended primarily for NIH personnel engaged in intramural laboratory and clinical investigation, past experience has shown the existence of a considerable external demand for copies of this Guide. To accommodate this demand more effectively, arrangements have been made with the U.S. Superintendent of Documents to place on sale single and bulk copies of the 1972 edition of the NIH Radiation Safety Guide.

National Institutes of Health Radiation Protection Guide

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine and research, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures.

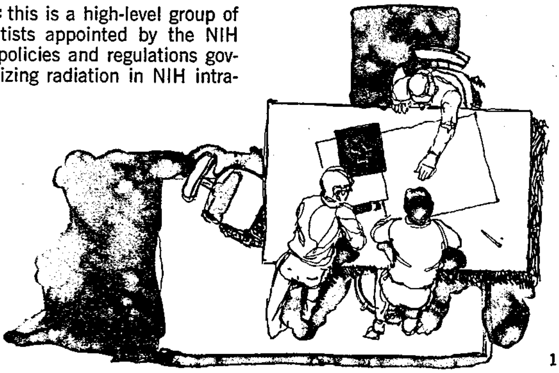
But unlike most other such hazards, the risk of unguarded exposure to ionizing radiation includes the possibility of damage to future generations. Thus the safety rules which govern all uses of ionizing radiation are as concerned with preventing genetic damage as with protecting the health of the exposed individual. When followed faithfully, these rules limit exposures of radiation workers to levels far below those which might cause any adverse somatic or genetic effects.

Because of the size and scope of its laboratory and clinical research programs, NIH is one of the world's largest users of ionizing radiation sources. These include radioisotopes, and isotope irradiators, x-ray machines, electron microscopes, and particle accelerators, all of which are essential to accomplishing the NIH mission.

The rules and procedures set forth in this Guide have one single, straightforward purpose—to protect NIH patients and employees against unnecessary and potentially harmful radiation exposure.

Four stages of group and individual responsibility are involved in the radiation safety program. All are equally important:

Radiation Committee: this is a high-level group of physicians and scientists appointed by the NIH Director to establish policies and regulations governing the use of ionizing radiation in NIH intramural programs.



Radiation Safety Office: an operating unit of especially trained health physicists and technicians which is responsible for NIH-wide compliance with these policies and regulations; it also provides a variety of technical services necessary to achieving such compliance.

Individual Users: physicians, scientists, other professionals, and technical and other workers engaged in patient care, clinical and laboratory research, and research support activities which involve actual use and handling of materials and devices producing ionizing radiation. These personnel usually work under the immediate supervision of Authorized Users.

Authorized Users: physicians and laboratory scientists whose training and experience are such that they have been authorized by the Radiation Committee to use ionizing radiation in their clinical care, clinical research, and laboratory research activities.

In the following pages detailed descriptions are given of the responsibilities of each of these four categories. Information is also provided on policies, rules and procedures for various particular aspects of ionizing radiation source procurement and usage. Careful observance of responsibilities, rules and procedures set forth in this Guide will insure more than adequate protection against unnecessary exposure to ionizing radiation.

Radiation Committee Responsibility

The Radiation Committee is composed of ten members appointed by the Director, NIH. The membership consists of one group of five physicians who are nominated by the Medical Board and, in conformity with AEC recommendations, is made up of one hematologist, one radiologist, one pathologist, one internist, and one physician with broad background in the use of radioisotopes. A second group of four scientists is nominated by the Scientific Directors. At least one of these scientists is to be a radiation physicist with training and experience in health protection. The Chairman of the Radiation Committee, the Radiation Safety Officer, and a representative of the Office of the Director are appointed by the Director, NIH. The Committee shall have jurisdiction over radiation sources and activities in areas under NIH control, including intramural program off-site use.

Functions

(a) Recommend policies regarding patient and plant radiation safety to the Director, NIH.

(b) Provide technical advice to the Radiation Safety Officer on matters regarding radiation safety.

(c) Receive, review, and act on all applications for the use of radiation sources in any areas used by NIH personnel. These sources include radioisotopes to be used in human subjects.

(d) Receive and review periodic reports from the Radiation Safety Officer on monitoring, contamination, and personnel exposure.

(e) Periodically review the overall use of radiation sources at NIH from the standpoint of operational hazards.

(f) Review all instances of alleged infraction of use and safety rules with the Radiation Safety Officer and the responsible Clinical and Scientific Directors before submitting reports or recommendations to the Director, NIH.

Radiation Safety Office Responsibility

The Radiation Safety office, under the direction of the NIH Radiation Safety Officer, is responsible for:

1. General surveillance of all health physics activities, including both personnel and environmental monitoring.

2. Furnishing consulting services to personnel at all levels of responsibility on all aspects of radiation protection.

3. Receiving, delivering, and shipping all radioactive materials coming to or leaving the NIH reservation.

4. Assaying and performing nuclidic purity checks on all radioactive materials to be used in humans for therapeutic purposes.

5. Monitoring all accelerators and other machines capable of producing penetrating radiations.

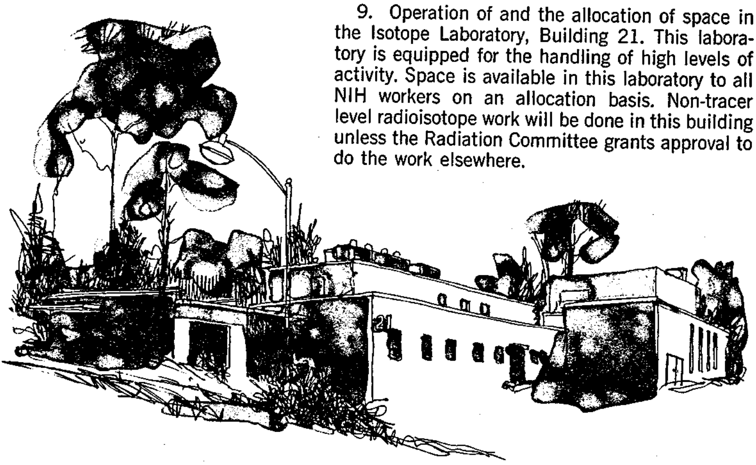
Calibrating the output of these machines as requested.

6. Distribution and processing of personnel monitoring equipment including the keeping of records of internal and external personnel exposure, and notifying individuals and their supervisors of exposures approaching the maximum permissible amounts and recommending appropriate remedial action.

7. Instructing personnel in proper procedures for the use of radioactive materials.

8. Supervision and coordination of the waste disposal program, including the keeping of waste storage and disposal records.

9. Operation of and the allocation of space in the Isotope Laboratory, Building 21. This laboratory is equipped for the handling of high levels of activity. Space is available in this laboratory to all NIH workers on an allocation basis. Non-tracer level radioisotope work will be done in this building unless the Radiation Committee grants approval to do the work elsewhere.



10. Storage of all radioactive materials not in current use.

11. Performing leak test on all sealed sources.

12. Maintaining a periodic inventory of all radioactive materials on the NIH reservation.

13. Supervising decontamination in cases of contaminating accidents.

14. Maintaining a continuous program of environmental radiation hazard evaluation and hazard elimination.

Individual User Responsibility

Each individual at NIH who has any contact with radioactive materials is responsible for:

1. Keeping his exposure to radiation as low as possible, and specifically below the maximum permissible exposure as listed in the following table:

	Rems per calendar quarter
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	1¼
Hands and forearms; feet and ankles	18¾
Skin of whole body	7½

Laboratory air and water concentrations shall be maintained below the levels listed in the Code of Federal Regulations, Title 10, Part 20 (10 CFR 20) "Standards for Protection Against Radiation." (See Appendix)

2. Wearing the prescribed monitoring equipment such as film badges and pocket dosimeters in radiation areas. Personnel who work only with pure alpha emitters or only with pure beta emitters having a maximum energy of less than 0.2 MeV will not be required to wear film badges.

3. Surveying his hands, shoes, and body for radioactivity, and removing all loose contamination before leaving the laboratory to smoke, eat, etc.

4. Utilizing all appropriate protective measures such as:
   - (a) Wearing protective clothing whenever contamination is possible, and not wearing such clothing outside of the laboratory area.
   - (b) Wearing gloves and respiratory protection when necessary.
   - (c) Using protective barriers and other shields whenever possible.
   - (d) Using mechanical devices whenever their aid will assist in reducing exposure.
   - (e) Using pipette filling devices. *Never pipette radioactive solutions by mouth.*
   - (f) Performing radioactive work within confines of an approved hood or glove box unless serious consideration has indicated the safety of working in the open.

5. Avoiding smoking or eating in isotope laboratories. It is recommended that eating be done in the cafeterias whenever possible. Smoking or eating may be permitted in an office area of a laboratory that has been demonstrated to be free of contamination. Refrigerators shall not be used jointly for foods and radioactive materials.

6. Maintaining good personal hygiene.
   - (a) Keep fingernails short and clean.
   - (b) Do not work with radioactive materials if there is a break in skin below the wrist.
   - (c) Wash hands and arms thoroughly before handling any object which goes to the mouth, nose, or eyes.

7. Checking the immediate areas, e.g., hoods, benches, etc., in which radioactive materials are being used, at least once daily for contamination. A log record should be maintained of these surveys including results which are entirely negative. Any contamination observed should be clearly marked and the Radiation Safety office notified.

8. Keeping the laboratory neat and clean. The work area should be free from equipment and materials not required for the immediate procedure. Keep or transport materials in such a manner as to prevent breakage or spillage (double container), and to insure adequate shielding. Wherever practical, keep work surfaces covered with absorbent material, preferably in a stainless steel tray or pan, to limit and collect spillage in case of accident.

9. Labeling and isolating radioactive waste and equipment, such as glassware, used in laboratories for radioactive materials. Once used for radioactive substances, equipment should not be used for other work, and *shall not be sent from the area to central cleaning facilities, repair shops, or to surplus, until demonstrated to be free of contamination.*

10. Requesting Radiation Safety office supervision of any emergency repair of contaminated equipment in the laboratory by shop personnel or by commercial service contractors. At no time shall servicing personnel be permitted to work on equipment in radiation areas without the presence of a member of the laboratory staff to provide specific information.

11. Reporting accidental inhalation, ingestion, or injury involving radioactive materials to his supervisor and the Radiation Safety office, and carrying out their recommended corrective measures. The individual shall cooperate in any and all attempts to evaluate his exposure.

12. Carrying out decontamination procedures when necessary, and for taking the necessary steps to prevent the spread of contamination to other areas.

13. Complying with requests from the Radiation Safety office for body burden measurements in the whole body counter and the submission of urine samples for radioassay. Requests for these tests will be made in the case of workers using significant quantities of both γ and β emitters.

Authorized User Responsibility

Authorized users are responsible for insuring that the preceding individual responsibilities are discharged by those under their control, and are further responsible for:

1. Adequate planning. Before an experiment is performed, the supervisor should determine the types and amount of radiation or radioactive material to be used. This will generally give a good indication of the protection required. The procedure must be well outlined. In many cases, before the procedure is actually performed with radiation, it should be rehearsed so as to preclude slip-ups or unexpected circumstances. In any situation where there is appreciable radiation hazard, the Radiation Safety office shall be consulted before proceeding.

2. Instructing those employees for whom they are responsible in the use of safe techniques and in the application of approved radiation safety practices.

3. Furnishing the Radiation Safety office with information concerning individuals and activities in their areas—particularly, pertinent changes in their personnel rosters.

4. Contacting the Radiation Safety office whenever major changes in operational procedures, new techniques, alterations in physical plant (e.g., the removal of radiochemical fume hood), or when new operations which might lead to personnel exposure are anticipated.

SAFTY & WASTE
DISPOSAL

5. Complying with the regulations governing the use of radioactive materials, as established by the AEC and the NIH Radiation Committee, for:
    - (a) Correct procedure for the procurement of radioactive materials by purchase or transfer. (See procedure for Procurement of Radiation Sources.)
    - (b) Posting areas where radioisotopes are kept or used, or where radiation fields may exist.
    - (c) Seeing that each sign carries the name of the personnel currently responsible for the associated area.
    - (d) Recording the receipt, transfer, and disposal of radioactive materials in his area. This includes sealed sources such as ion sources in gas chromatographs and static eliminators. The authorized user must be prepared to submit semiannually the required inventory data upon request.
    - (e) Assuring that all radioactive waste materials are consigned to the Radiation Safety office for disposal.
    - (f) Taking steps to prevent the transfer of radioactive materials to unauthorized individuals. This includes the proper disposition of radioactive materials possessed by terminating workers.

6. Keeping stocks of stored radioactive materials to a minimum within laboratory areas. Authorized users should employ the storage facilities of the Isotope Laboratory, Building 21, for shipments not needed in current research.

7. Complying with proper procedure for termination of employment or termination of any experiment using radioactive materials. The authorized user is reminded that, under the terms and conditions of the AEC-NIH license, he must return to the Radiation Safety office all radioactive materials, including waste, assigned to him under the license. Particular care should also be exercised to see that specialized equipment such as personnel monitoring devices (e.g., film badges), survey instruments, and shielding materials are returned to the Radiation Safety office. A final termination survey should also be requested by telephone.

Policies and Procedures for Radioisotope Areas

In addition to the Code of Federal Regulations, Title 10, Part 20, "Standards for Protection Against Radiation," as appended to the Guide, the following policies and procedures will apply to the NIH license:

1. Proper Marking of Laboratories, Areas, and Equipment

   (a) A "CAUTION RADIOACTIVE MATERIALS" sign must be conspicuously posted on the doors to laboratory areas where radioactive materials are being used or stored. The name and home phone number of the individual responsible for the posted area shall be shown in the designated place on the sign in order to facilitate contact in case of emergency. The supervisor shall be responsible for seeing that the posted information is current. The signs must not be removed from any room except by Radiation Safety personnel following an inspection survey.

   (b) Storage areas shall be conspicuously marked with a "CAUTION RADIOACTIVE MATERIALS" sign. In addition, containers in which materials are transported or stored shall bear a durable, clearly visible label bearing the radiation caution symbol and the words "CAUTION RADIOACTIVE MATERIALS." This label shall also state the quantities and kinds of radioactive materials in the containers and the date of measurement of the quantity.

   (c) Radiation areas in the laboratory, i.e., areas where radiation levels might expose individuals to 5 millirem in any one hour; or in any five consecutive days, a dose in excess of 100 mrem, shall be posted with the sign "CAUTION RADIATION AREA."

   (d) All equipment contaminated with radioactive material shall be marked with signs, decals, or other conspicuous means. Labeling shall not be required for laboratory containers such as beakers, flasks, and test tubes, used transiently in laboratory procedures during the presence of the user.

(e) All signs referred to in this part are available from the Radiation Safety office, Building 21.

2. Shielding of Sources

(a) Radioactive sources or stock solutions in the laboratory shall be shielded in such a manner that the radiation levels in any occupied area will not expose individuals in the area to more than 100 mrem in any five consecutive days.

(b) Various shielding materials are available on loan from the Radiation Safety office.

3. Aerosols, Dusts, and Gaseous Products

(a) Procedures involving aerosols, dusts or gaseous products, or procedures which might produce airborne contamination shall be conducted in a hood, dry box, or other suitable closed system.

(b) All releases from such systems shall not exceed the maximum permissible concentration in air for the nuclide in question. See Appendix B, Table II of 10 CFR 20 for appropriate values. However, where practical, traps should be incorporated in the experimental set-up to insure that environmental releases are as low as possible.

(c) Radioactive gases or materials with radioactive gaseous daughters must be stored in gas-tight containers and must be kept in areas having approved ventilation.

(d) Hoods to be used for radioisotope work should be tested by the Environmental Services Branch, DRS, to insure that they meet the minimum requirements for air velocity at the face of the hood.

4. Sealed Radioactive Sources

(a) All sealed radioactive sources must be shipped to: Radiation Safety Officer, National Institutes of Health, Building 21, Isotope Laboratory, Bethesda, Maryland 20014. Each source must be registered with this office.

(b) For those sources which may change location frequently, the Radiation Safety office in cooperation with individual users shall establish strict accountability procedures.

(c) Sealed sources shall be leak tested by Radiation Safety personnel prior to initial use and at least every six months thereafter.

5. Radioactive Materials in Gas Chromatography Equipment

All gas chromatography units in which radioactive materials are to be used are regulated as follows:

(a) As is true with other radioactive shipments, radioactive foils to be used in gas chromatography cells must be shipped to: Radiation Safety Officer, National Institutes of Health, Building 21, Isotope Laboratory, Bethesda, Maryland 20014. Each foil must be registered by number with this office.

(b) In addition, each cell containing a radioactive foil must have a label showing:

The radiation caution symbol with the words "CAUTION RADIOACTIVE MATERIAL"; and

The identity and activity of the radioactive material.

The radioactive foil shall not be removed from its identifying cell except for cleaning and shall not be transferred to other cells.

(c) The following notice shall appear in a conspicuous location on the outside of each gas chromatography unit: "This equipment contains a radioactive source registered with the NIH Radiation Safety office as required by license from the Atomic Energy Commission. Notify the Radiation Safety office before removing the source from this room or area or upon any change in custodial responsibility." These notification tags are available from the Radiation Safety office, Building 21.

(d) Individuals using radioactive components in gas chromatography equipment must vent the cell-exhaust through plastic tubing into a hood, room exhaust, or Radiation Safety approved trap, to avoid contamination of work areas from the release of radioactive tagged samples introduced into the system or from the accidental overheating of radioactive foils in the cells.

(e) The Radiation Safety office will perform periodic leak tests, store radioactive foils when not in use, and maintain the necessary records on such tests and storage.

6. Work Surfaces

All work areas (bench tops, hood floors, etc.) as well as storage areas and areas adjacent to permanent set-ups and sinks should be covered at all times with stainless steel or plastic trays, uncracked glass plates, or other impervious materials. For some purposes a plastic-backed absorbent paper (e.g., "Kimpak", available from the Central Storeroom) will be satisfactory. However, if such paper is used, it should be discarded frequently to prevent active materials from dusting off the surface.

7. Periodic Surveys of Radiation Areas

The immediate areas (e.g., hoods, bench tops) in which radioactive materials are being used should be checked for contamination at least once daily by the radiation workers in that laboratory. In addition, these areas should be inspected each and every time there is reason to suspect a contamination incident. *Records shall be kept on both positive and negative survey results in the authorized user's laboratory logs.*

8. Laboratory Monitors

Each laboratory or area (other than those where ^{3}H is used exclusively or where only exempt quantities of other radionuclides are handled) shall be equipped with a portable or semiportable monitoring device to be used for personnel and area monitoring. Laboratory monitors of this type are available on loan from the Radiation Safety office.

9. Removal of Equipment from the Laboratory

Once used for radioactive substances, equipment shall not be used for other work, or sent from the area to central cleaning facilities, repair shops, surplus, or returned to the source of supply, until demonstrated to be free of contamination. Equipment to be removed from the Isotope Laboratory, Building 21, must be cleared through the Radiation Safety office.

10. Repair and Maintenance of Equipment in the Laboratory

Equipment to be repaired by shop and maintenance personnel, or by commercial service contractors, shall be demonstrated to be free of contamination prior to servicing. If it becomes necessary to make emergency repairs on contaminated equipment, the work will be supervised by a member of the Radiation Safety office staff, who will assure that the necessary safeguards are taken. It is the responsibility of the laboratory personnel to request this supervision from the Radiation Safety office.

11. House Vacuum Lines

House vacuum lines are vulnerable to contamination. If house vacuum lines are to be used, the withdrawn gas must be demonstrated to the Radiation Safety office to be free of radioactivity. It is advisable to use a separate vacuum system whenever possible, such as a separate vacuum pump exhausting into a hood.

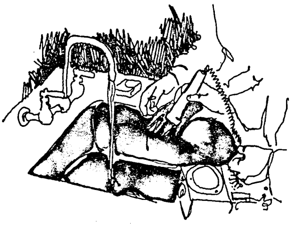
12. Radioactive Contamination of Areas

In general, no radioactive contamination can be tolerated. Exceptions to this will include certain hood trays, dry boxes, stainless steel trays, Kimpak covered surfaces, or other equipment which is used frequently for active work and which will be clearly marked with the standard radiation caution signs or stickers. Any contamination that is not confined to protected surfaces should be reported immediately to the Radiation Safety office. The Radiation Safety staff will supervise the decontamination of such areas or equipment.

13. Decontamination of Areas Contaminated with Radioactivity

Preparations for decontamination should be begun promptly. Determine the extent and 13 hazard of contamination. The Radiation Safety office staff will assist in this evaluation. The individual responsible for the contamination will be expected to do most of the cleanup under the supervision of the Radiation Safety staff. After decontamination, the area or equipment shall be considered contaminated until proved otherwise by the Radiation Safety office.

14. Decontamination of Personnel Contaminated with Radioactivity



(a) Notify supervisor immediately after contaminating accident.

(b) Wash body area involved thoroughly for 2 or 3 minutes, repeatedly "soaping" and rinsing. Consideration should be given to the chemistry of the contaminant and an attempt made to find a suitable agent for dissolving it. Any cleansing agent may be used, but synthetic detergents are preferred to soaps. Avoid prolonged use of any one decontamination procedure. Irritation of the skin may impede the success of more suitable procedures. Avoid the use of organic solvents. They may make the skin more permeable to radioactive contaminants.

(c) If this procedure is not immediately and completely effective, notify the Radiation Safety office and proceed at once to the Medical Officer in charge of the Building 10 Health Unit, Employee Health Service. Special decontaminating agents such as "Versene", "Radiacwash", etc. may be used under the direction of the Medical Officer.

15. Prophylactic Thyroid Blocking Agents in Laboratories Using Radioiodine

Individuals utilizing greater than 10mCi radioiodine should consult with and follow the recommendations of the Employee Health Service prior to the use of prophylactic thyroid blocking agents. Such individuals are reminded that the use of these blocking agents in no way reduces the need to take all other precautions in the safe handling of radioiodine.

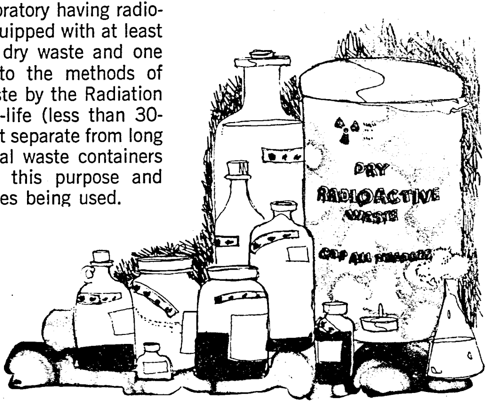
Radioactive Waste

No radioactive wastes shall be disposed of by conventional methods. This means particularly that solid wastes may not be placed in the standard waste containers to be collected by housekeeping personnel, and that liquid wastes may not be discharged into the sewer. Animals must not be incinerated in the general purpose incinerator.

No radioactive waste shall be released from a laboratory area for pickup and disposal prior to autoclaving or otherwise suitable deactivation of infectious agent(s). Radioactive waste disposal procedures in the waste handling area of the Isotope Laboratory, Building 21, involve crushing and compacting of dry wastes by compaction devices and pooling of liquids in approved shipping containers for disposal by a licensed contractor. These procedures are not compatible with the proper handling of infectious agents. Similar considerations shall also be given to other highly toxic or hazardous substances. (See Section 3)

1. Waste Containers

   To insure that solid and liquid wastes are kept separate, each laboratory having radioactive waste must be equipped with at least one container for solid dry waste and one for liquid waste. Due to the methods of ultimate disposal of waste by the Radiation Safety office, short half-life (less than 30-days) waste must be kept separate from long half-life waste. Additional waste containers shall be requested for this purpose and marked as to the isotopes being used.



   (a) Solid dry waste containers. These may be obtained from the Radiation Safety office. They must be kept fitted with a disposable waterproof polyethylene liner.

   (b) Liquid waste containers. Plastic carboys, glass jars, or bottles are suitable for storage of liquid wastes. If the liquid waste container is glass or ceramic, then it must be kept in such a manner that if accidentally broken, the contents will be retained in a small area, e.g., having it set in a large pan. These liquid containers must possess securely fitting covers or corks, and must be kept closed. In addition, they shall be conspicuously marked with appropriate radiation signs.

(c) Animal carcasses. Small radioactive animals should be placed in the standard polyethylene bags. Larger animals (dogs, etc.) should be placed in large polyethylene bags which will in turn be placed in a GI can. Each unit must be conspicuously marked with a "CAUTION RADIOACTIVE MATERIAL" sign and in addition, the isotope(s) and amount remaining in the carcass shall be posted on the bag or label. If pickup cannot be arranged within 4 hours of sacrifice of animals, such animal carcasses must be refrigerated or preferably frozen.

(d) Liquid scintillation vials. All liquid scintillation vials must be disposed of as radioactive waste. Prior to removal, all liquid scintillation vials must be tightly capped and returned to the original shipping trays.

2. Waste Pickup

Request for removal of liquid and dry waste may be made by telephone to the Radiation Safety office. At the time of the telephone request and at time of pickup, the investigator must be able to estimate, with a fair degree of accuracy, the amount of radioactive waste in each container.

3. Unusual Waste Disposal Problems

Plans for proper disposal of infectious agents or highly toxic or hazardous substances shall be made early in the design stage of the experiment.

Proposed procedures involving unusual waste disposal problems will be considered individually by the Radiation Committee or the Radiation Safety Officer and staff.

Physician's Responsibility and Procedures

In carrying out the responsibilities and duties assigned it by the AEC under the Broad License and by the Director, NIH, the Radiation Committee requires compliance with the following policies and procedures:

1. Experience and Training of Applicants

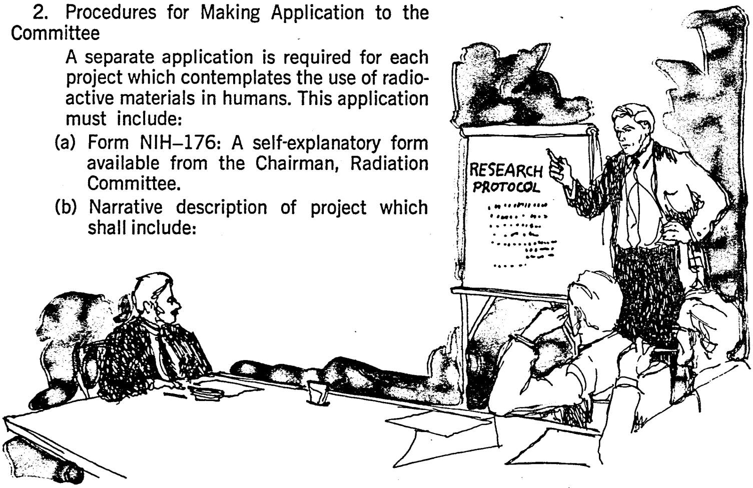
   The Committee is bound by the requirements of AEC for training and experience of physicians in the use of radioactive materials. These requirements are listed in "Atomic Energy Commission Licensing Guide—Medical Programs," November 1965. Copies of this report are available for reference from both the Radiation Committee office and the Radiation Safety office.

2. Procedures for Making Application to the Committee

   A separate application is required for each project which contemplates the use of radioactive materials in humans. This application must include:

   (a) Form NIH–176: A self-explanatory form available from the Chairman, Radiation Committee.

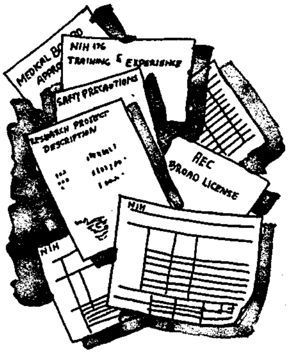
   (b) Narrative description of project which shall include:



   (1) Title of the project.

   (2) A statement of the purpose and justification for the use of radionuclides.

   (3) Description of the project; including methods, characteristics of radioactive materials (half-life, nature and energy of emissions, modes of decay), details of doses (single and total) and



the anticipated results. Reference to previous work published by the Applicant or others concerning animal experimentation or human use (including doses) should be carefully documented. The Committee requires a clear, concise calculation of the anticipated whole body and critical organ absorbed dose in rads, stating the period of such exposure and radiation hazards, if any. Include uptake and excretion data. The formula used for such calculation should be clear, all terms defined, and the source and estimated reliability of the formula indicated. Assumptions used for estimates should be stated. Assay methods and estimated efficiencies should be given.

(4) Methods of waste disposal, particularly with respect to urine, stools, exhaled air, and calculation of the daily amounts of radioactivity to be disposed of into the sewer or air, if any.

(5) Safety precautions which will be initiated to protect the patient, other patients in the vicinity of the radioactive patient, and the patient-care staff and adjunct personnel.

(6) If the use of the radioactive material is planned for normal human subjects, the application must specify minimum ages of these subjects, the fact that they are volunteers, cognizant of the possible radiation hazards, and the status of such normal subjects with respect to other contacts with radiation, and cumulative exposure. In addition, the Radiation Committee requires a short statement from the investigator regarding the information he would supply to the volunteer pursuant to obtaining his consent.

(c) With the first application from each investigator, a complete description of his training and experience, stating periods, location and supervision in the use of radionuclides (Form NIH–465–1,–2).

Upon completion, this application should be forwarded through the Branch Chief, and the Clinical Director of the applicant's Institute to the Chairman of the Radiation Committee. Action of the Committee will be returned through channels to the applicant and copies will be forwarded to the Radiation Safety Officer and to the Chief, Radiopharmaceutical Section. The signed approved original will constitute the investigator's authorization under the Broad AEC License to procure and use the materials. Physicians may obtain information on current approved investigators and specific medical uses at NIH from the Radiation Committee office.

Should questions arise in the Committee regarding details of an application, the investigator will be invited to meet with the Committee and discuss the details of his proposal. Should the Committee finally disapprove the application on the basis of conflict with restrictions of the AEC or Director, NIH, or Committee policies, the application nevertheless will be forwarded to AEC for its review and action upon further recommendation of the investigator and his Clinical Director.

Each authorization will be marked with an expiration date which will usually be the last day of the month, one year after the month of the approval. Authorized investigators should anticipate the expiration of their approvals by at least one month and apply for renewal of the authorization. For this purpose, it is necessary to submit only the Form NIH-176 (without narrative description) and a "Summary of Use of Radioactive Materials," Form NIH-465-3. The investigator should clearly state that this is an application for renewal of the previous authorization without modification, and should include the number of the original authorization and date.

If an investigator has no positive plans for the use of a given authorization during the coming year, he should consider its retirement in order to save on bookkeeping in the Radiation Committee, Radiation Safety and Radiopharmacy offices. Such a retired authorization can usually be reactivated by the Chairman, Radiation Committee, in one day should need for it develop.

An authorization which is being considered for renewal and which reflects frequent patient use may be retained and established as a service to be provided to the clinician and patient by the Department of Nuclear Medicine. Decision to provide this service will reside with the Chief, Department of Nuclear Medicine. This service consideration would also be applied in the situation where several similar authorizations by separate applicants reflect an overall need for patient service from various areas of the Clinical Center.

After receiving the approved Form NIH–176, the investigator should comply with the procedures "Procurement of Radiation Sources" listed elsewhere in this Guide.

3. Responsibility

   The authorized investigator has primary responsibility for the use of the radioactive material; for the protection of the patient, and for the safe handling of any material removed for study. The Radiation Safety staff is responsible for the protection of the patient-care staff, for instructions needed to insure radiation-safe conditions, and for the handling of contaminated materials, equipment, and waste. *Any delegation of work does not shift responsibility.*

   Special instructions regarding patient treatment shall be on Clinical Record SF–508. Radiological safety precautions will be recorded on Form NIH–876.

4. Justification

   The widely accepted policy for medical uses of radioisotopes is that radioactive substances should never be used in humans except when the investigation or treatment justifies the risk involved. It is NIH policy to encourage use of the most sensitive instrumentation and assay procedures available, and to promote progressively better techniques aimed at reducing radiation doses. All research and diagnostic procedures should be designed with these policies in mind.

   The therapeutic uses of radiation in other than malignant disease should be well justified. Applications for therapeutic uses of radiation will be reviewed by the Radiation Committee in accordance with instructions from the Director, NIH, and the Medical Board.

5. Dosage Considerations

   As a general guide to the maximum permissible dose for normal volunteers and for patients, the Radiation Committee follows the recommendations of the National Council on Radiation Protection and Measurements Report No. 39, "Basic Radiation Protection Criteria." Insofar as is practical, the Committee considers that exposure of normal subjects and patients should be limited to these values when diagnostic and experimental purposes permit. When it is necessary to exceed this dosage for the purposes of research or diagnosis because instrumentation of the required sensitivity is not available, the applicant will be required to provide justification for exposures higher than 3.0 rads to any tissue within a 13-week period, and if such exposure occurs in a single dose, assurance that the human subject or patient will not receive further radiation for a subsequent period of one year. For all normal subjects and patients under the age of 18 years and all pregnant women, this limit is reduced to 0.30 rads.

Larger doses will be considered by the Committee for use in patients with limited life expectancy (two years or less) when the application adequately justifies the procedure and the importance of the contribution which is anticipated by the use of such doses.

When considering the utilization of radioactive materials for human research and diagnosis, the investigator is urged to carefully consider the following factors:

- (a) Body retention of the radioactive materials.
- (b) Accumulation in critical tissues.
- (c) Size of critical organ.
- (d) Radiosensitivity of the tissue.
- (e) Biological half-life.
- (f) Effective half-life.
- (g) Type and energy of the radiations.
- (h) Accumulation of effects of combined or sequentially administered radioactive materials.
- (i) Concomitant use of x-radiation.

6. Calibration and Nuclidic Purity Tests

   Prior to administration, all radionuclides are to be calibrated and tested for nuclidic purity by the Radiopharmaceutical Section. Indicated pyrogen and sterility testing is to be arranged by the Radiopharmaceutical Section.

7. Notification of Nursing Staff

   In order that the nursing staff may prepare for therapeutic isotope administration, the head nurse of the nursing unit which will care for the patient should be notified as far in advance as possible, preferably 24 hours or more. Those connected with the administration of radioactive isotopes should become familiar with nursing procedures to insure uniformity of precautions.

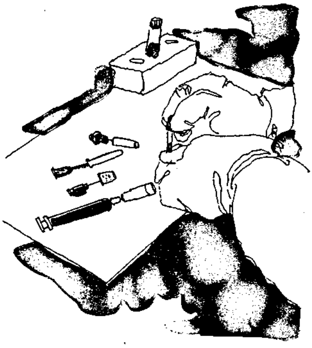
8. Area Designation

   It is not necessary to isolate patients with routine diagnostic doses nor to post their rooms. Patients with therapeutic doses should be confined to their individual rooms, as distant from the nursing station as feasible, and the room posted with a "Radiotherapy Precautions" sign (available from the Radiation Safety staff). The Radiation Safety staff will conduct daily surveys of the patient area following therapeutic doses, removing contaminated materials such as urine, soiled bedding, etc., when necessary, and instituting controls so that the patient-care staff, adjunct personnel, and visitors are not exposed to radiation levels in excess of applicable guides. The physician in charge is responsible for requesting assistance from the Radiation Safety staff in the event of contaminating accidents, and prior to removal of the patient from therapy precautions.

9. Record of Patient Doses
The authorization number and any dose of a radioisotope administered to a patient together with the other required data shall be recorded immediately on the patient's chart using Form PHS–2201, "Radioactive Isotope Exposure Record."

10. Radioactive Waste and Disposal
Radioactive contamination of room air and sewerage should not exceed the limits approved by the AEC as stated in 10 CFR 20 (found elsewhere in this Guide). When wastes exceed these limits, they shall be disposed of with the assistance of the Radiation Safety staff.

11. Radioactive Contaminated Equipment
The authorized physician is responsible for arranging for the safe disposal of all radioactive solutions and contaminated equipment such as syringes, etc. This may be accomplished by removal to the individual's laboratory for proper decontamination or storage for decay, or by contacting the Radiation Safety staff for disposal. Under no circumstances should such solutions or equipment be left on the nursing unit, or the responsibility for disposal of these materials be delegated to the nursing staff. The Radiation Safety Officer strongly recommends the use of disposable syringes and needles for the administration of radionuclides. Disposable syringes containing only the usual residual fluid may be disposed of in the regular dry radioactive waste containers available on the nursing units. Disposable needles may also be put into the regular dry radioactive waste containers ONLY after they have been capped or after the needle point



has been inserted in a small cork. This is necessary in order to preserve the integrity of the plastic bag lining the container and to protect personnel handling these liners.

12. Laboratory Specimens

There exists a danger that highly radioactive tissue specimens, blood, ascitic fluid, excreta, or cadavers may be delivered to the laboratory or pathology services, without being adequately labeled. To minimize this possibility, all specimens from such patients which are to be sent to a laboratory must be labeled "Radioactive." Preferably, the laboratory should be called in advance to give them additional information, such as the amount of activity and special handling techniques required, if any. This includes tissue specimens, ascitic fluid, blood, urine, feces, emesis, etc.

Exemptions:

(a) When the time elapsed between the administration of the radionuclide and the time of obtaining the specimen is such as to render the specimen (in the opinion of the physician in charge of the patient or in the opinion of the Radiation Safety Officer) no longer a hazard from either a health or a contamination standpoint.

(b) When the radionuclide is administered in such a way that it remains localized and does not enter significantly into the general circulation (such as colloidal gold injected into the prostate), and the specimen is excreta or a tissue removed at a site sufficiently distant from the injection site so that it is unlikely to contain any of the radioactive material.

13. Cadavers

If a patient who has received a therapeutic dose of any radioisotope dies in the hospital within a three (3) week period after that dose, the authorized physician is requested to do the following:

(a) Tie a radioactive hazard sign to the body writing on it the specific isotope, the amount given, and the date of administration.

(b) Place the Form PHS–2201 as the top sheet in the chart and write across the face of this sheet "Radioactive Body."

(c) Notify the Radiation Safety Officer. During off-duty hours the Guard Office in Building 31 should be requested to notify one of the persons on the call list maintained for such emergencies. The Radiation Safety Officer must be notified as he is responsible for giving the pathologist suitable safety instructions and for giving the required information to the funeral director.

Procedures for Nursing and Patient Care Staff

1. Diagnostic Procedures

Since there is minimal external hazard to others from routine diagnostic doses of radionuclides, there are no restrictions on the patient's activities or his contacts with other people. Nursing personnel are not required to wear personnel monitoring devices.

The following procedures apply when a patient receives radioactive material for diagnostic purposes:

(a) The Chief Nurse of the unit should request a Geiger counter and dry radioactive waste can from the Radiation Safety staff to be kept in the utility room.

(b) Patient-care personnel should use disposable gloves to handle items suspected of contamination. Particular care should be exercised in the handling of vomitus and excreta during the first 24 hours following administration of the radionuclide. Use the Geiger counter to check for contamination. Contaminated linen should be placed in a yellow laundry bag which is kept in the patient's room. Other contaminated items should be placed in the radioactive waste container. Call the Radiation Safety office for removal of such contaminated linen and waste.

(c) Laboratory samples taken during the first 24 hours post administration should be labeled "Radioactive."

(d) Special diagnostic procedures will be evaluated on an individual basis and appropriate written instructions may be issued.

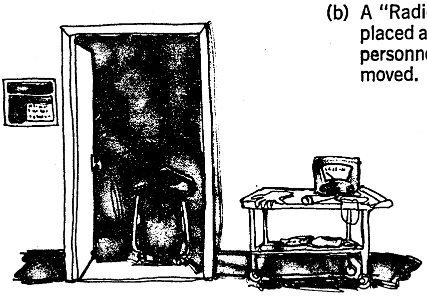
(e) Should questions arise concerning the use of radionuclides on a unit, call the Radiation Safety staff for assistance.

2. Therapy Procedures

The following procedures apply when patients receive radionuclides other than sealed sources or colloidal suspensions, in millicurie amounts for therapeutic purposes:

(a) Special Radiation Safety Procedures (Form NIH–876) will be issued to the Chief Nurse of the unit at the time the radioisotope is given or at the time the patient is returned from the operating room. This form will indicate precautions to be taken on a daily basis and will be reviewed each day by Radiation Safety personnel.

(b) A "Radiotherapy Precautions" sign shall be placed at the patient's door. Radiation Safety personnel will indicate when it may be removed.



(c) The patient should be put in a room by himself. For patients receiving gamma-emitting nuclides, this room should be as distant from the nursing station as feasible. *Exception:* Patients receiving radiation source implants (radium or iridium needles) or colloidal suspensions may be placed in a room with another patient providing this second patient is receiving external beam therapy.

(d) Handling of Patient

1. When indicated on the Form NIH–876, the patient-care staff should wear dis-

posable gloves while handling the patient. Used gloves should be placed in the radioactive waste can for disposal.

2. Wash hands thoroughly with soap and running water after gloves are removed.
3. After handling the patient, patient-care personnel should monitor themselves thoroughly using the Geiger counter provided for this purpose.

(e) Food Service

If feasible, paper plates and disposable utensils should be used by the patient during therapy precautions. If found contaminated after use, they should be placed in the waste container provided for this purpose.

(f) Patient's Linen

All linen, i.e., bedclothes, pajamas, towels, etc., used during the period of therapy precautions must be placed in a yellow laundry bag to be kept in the patient's room, and must not be sent to the laundry until monitored by Radiation Safety personnel.

(g) Removal of Objects and Materials From Patient's Room

All objects or materials to be removed from the therapy precautions area shall be checked for contamination. It may be necessary to remove these articles temporarily to the utility room for monitoring, due to the radiation levels in the vicinity of the patient.

(h) Disposal of Radioactive Excreta

1. Feces should be passed in the toilet whenever possible. If a bedpan is used, it must be handled with disposable gloves. The same bedpan should be used until treatment is completed and its use restricted to that particular patient.
2. Urine shall be saved in stoppered bottles and if the isotope is a gamma-emitter, the bottles shall be kept in a shielded storage container provided by the Radiation Safety staff. Urine container, urinals, specimen bottles, etc., should be handled only by the patient if at all possible.

(i) Housekeeping Personnel
Housekeeping personnel shall not enter the room unless indicated on the Form NIH-876.

(j) Accidents
In case of an accident which might produce a radiation hazard (e.g., the spillage of contaminated urine on the floor),

CALL AT ONCE:
During Regular Working Hours
The Physician in Charge,
Radiation Safety Officer,
and
Chief of Nursing Service.
Outside of Regular Working Hours:
Nursing Supervisor in Charge,
Physician in Charge,
and
Guard Office in Building 31 for names of
Radiation Safety office personnel on call.

3. Colloidal Suspensions and Sealed Sources

The following apply when patients receive therapy utilizing colloidal suspensions or sealed sources, such as needles, tubes and plaques containing iridium-192, cobalt-60, radium, radon, etc.:

(a) All dressings, bedclothes, sanitary napkins, bedpans, etc., or any material removed from the vicinity of the treatment site shall be carefully monitored to assure that the source has not been removed or displaced.

(b) The above-mentioned items (a), (b), (c), and (i) of Part 2 shall also apply.

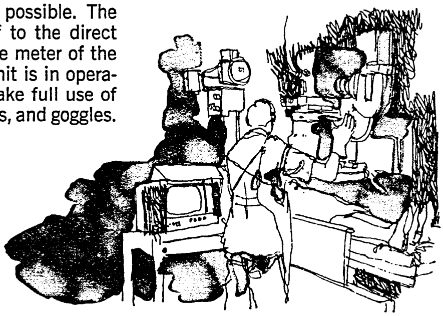
(c) Items (d), (e), (f), (g), and (h) do not apply to these cases since there is little if any chance of contamination.

(d) The nursing staff should be alert to any sealed sources which may have moved from their original positions. Should an implanted source become separated from the patient, proceed as in 2-(j) above.

Radiation Producing Equipment Operator's Responsibility

The operator of any radiation producing equipment is responsible for:

1. Notifying the Radiation Safety office when there is any change in the setup, i.e., new equipment installed, changes in shielding, change in output of radiation, or change in usage of the unit.
2. Requesting and wearing appropriate monitoring devices. Always wear the assigned monitoring device (e.g., film badge) when working with the unit. Whenever protective lead aprons are worn, the body monitor should be worn on the outside of the apron at the neckline. In addition, wrist monitors are to be worn if the unprotected hands and forearms must come in close proximity to the beam.
3. Keeping exposure as low as possible. The operator must never expose himself to the direct beam, and must not stand within one meter of the tube or irradiated target while the unit is in operations unless adequately shielded. Make full use of protective barriers, lead aprons, gloves, and goggles.



4. Clearing the area of all nonessential personnel. The operator should insist that all nonessential personnel leave the exposure area before operating the unit, and that all essential personnel be adequately shielded.
5. Observing any restrictions on the use of the unit recommended by the Radiation Safety staff.
6. Adequate dark adaptation. The eyes of the fluoroscopist should be well dark-adapted before he uses a fluoroscope without image intensifying equipment. It is inexcusable to increase the output of the unit to compensate for poor dark adaptation.
7. Using minimum exposure factors. Fluoroscopic work shall be performed in the minimum time possible using the lowest dose rate and smallest aperture consistent with clinical requirements.

8. Visually monitoring tube current and potential of fluoroscopic equipment with image intensifiers at frequent intervals, because under automatic brightness control these variables can rise to high values.

9. Recording data of fluoroscopic and cineradiographic studies on patients on Form NIH-378, "Radiation Exposure Record," and maintaining this form in the patient's record.

10. Notifying the supervisor and the Radiation Safety Officer immediately of any accidental exposures to radiation.

11. Keeping the unit disconnected or locked when not in actual use.

Policies for Radiation Producing Machines and Areas

1. All operating personnel and personnel in the immediate area will be required to wear a film badge or other personnel monitoring device.

2. Areas in which radiation producing machines are located or are being used shall be posted with the characteristic "CAUTION RADIATION" sign. In addition, the controls shall bear a decal with the statement: "CAUTION RADIATION—This equipment produces radiation when energized." Labels and decals are available from the Radiation Safety office.

> ***Exception:*** Diagnostic and patient treatment areas need not be so marked, provided that a person is charged with the responsibility for protection of employees, patients, and authorized visitors against radiation injuries, and for the execution of Radiation Safety recommendations.

3. The structural shielding requirements of any new installation, or an existing one in which changes are contemplated, shall be discussed with the Radiation Safety staff.

4. An annual, scheduled survey of all radiation producing equipment used on patients shall be made by Radiation Safety personnel. In addition, radiation surveys will be made of all new installations and all existing installations after every change that might increase the radiation hazard

(e.g., replacement of x-ray tube, changes in filtration of beam).

5. Unless measurements indicate that they are not needed, protective aprons shall be worn by the physician, nurse, technician, and all other persons within the room or area who are frequently or habitually exposed to radiation.

6. Dose rates for the beam shall be determined for all units used on human subjects and will be reported to the operator in milliroentgens per milliampere-second or milliroentgens per minute. The "Radiation Exposure Record," Form NIH-378, shall be completed for fluoroscopic and cineradiographic studies and maintained in the patient's record.

7. In the operation of mobile and dental units:
   (a) The operator should stand as far as possible from the tube and patient during exposure, and should wear a protective apron, or step behind an adequate shield.
   (b) An operator, standing at least 6 feet from the tube and patient, should not make more than 5,000 milliampere-seconds of exposure during any one week. Rotation of operators or the use of portable shields is recommended for greater workloads.

8. The hand of the fluoroscopist should never be placed in the useful beam unless the beam is attenuated by the patient and a protective glove of at least 0.25 mm lead equivalent is worn.

9. No person shall be regularly employed to hold patients during exposure, nor shall anyone from the Diagnostic Radiology Department ever be permitted to perform such service. The person holding the patient shall wear protective gloves and a protective apron. No part of this person's body should be in the unattenuated useful beam.

10. If safe use of the installation depends upon mechanical restriction of the orientation of the radiation beam, or upon limitations (voltage, current, time, permanent filter, and maximum aperture) in the output of the unit, then these restricions shall be rigidly followed.

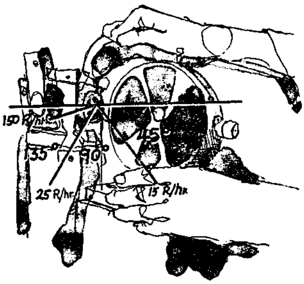
11. Shutter mechanisms and interlocking devices should not be tampered with and shall be inspected at frequent intervals to insure proper operation.

12. All protective devices that may become defective due to use or abuse, such as protective lead aprons or gloves, should be inspected for radiation leakage at least every six months, or whenever the integrity of the equipment is suspect.

13. A manually reset cumulative timing device shall be used which will either indicate elapsed time or turn off the apparatus when the total exposure reaches a certain previously determined limit.

14. In cineradiography, tube currents and potentials are often higher than those used in fluoroscopy. Thus, special care should be taken to limit patient exposure. The exposure rates on these cineradiography units shall be determined during the annual survey.

15. X-ray diffraction equipment can be particularly hazardous because of high exposure rates in the primary beam (e.g., in excess of 500,000 roentgens per minute at the x-ray tube port).



(a) A radiation survey shall be made by the Radiation Safety staff before a new installation is placed in routine operation and whenever changes are made which could adversely affect radiation protection. The equipment shall be frequently inspected for radiation leakage and a radiation survey shall be made at least annually by Radiation Safety personnel.

(b) Appropriate operating procedures and safety measures approved by the Radiation Committee shall be established and followed for these units.

16. Personnel specifically responsible for such equipment shall insure that all workers in the area are monitored in accordance with the requirements for the specific unit.

17. For larger, individually licensed irradiators and accelerators, specific operating and emergency procedures shall be established and posted. All users of this equipment shall operate it in compliance with these posted instructions.

18. All interlocks, visual and audible warning devices, and monitoring equipment shall be inspected for proper operation at six month intervals by Radiation Safety personnel.

Procurement of Radiation Sources

The following procedures for the procurement of radiation sources are intended to insure compliance with the terms and conditions of the license issued by AEC, and the regulations imposed by the Director, NIH:

1. The Radiation Safety Officer must be notified in advance of the procurement of all radiation sources whether ionizing radiation producing machines, AEC-licensable or accelerator-produced isotopes, radium, or other radioactive materials.

2. When the use of radiation sources is planned, the investigator must indicate to the Radiation Committee his training and experience in this area. This is done by submitting one copy of the Form NIH–465 to the Radiation Safety office. When the investigator makes application to the Committee, it is understood that *he accepts the responsibility for complying with the regulations governing the safe use of sources in NIH controlled areas.*

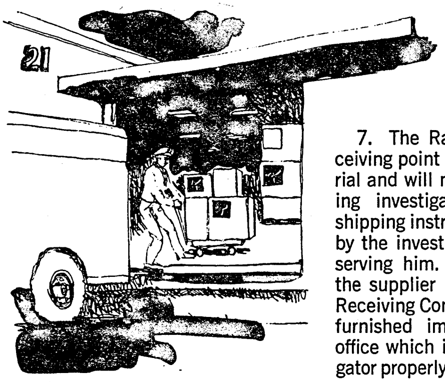
3. Upon notification of approval of his qualifications, the investigator then submits Form NIH–88, "Application for Use of Radioisotopes at the National Institutes of Health," to the Radiation Safety office. The form covers only the quantities specified on a single requisition. The form must be completed regardless of the method of acquisition. In cases other than purchase, the form serves as the required notice to the Radiation Safety office that the receipt of radioactive materials is contemplated through gifts or transfers from any source.

4. Established users of the NIH license may procure radioisotopes under the Telephone Charge Order (TCO) system, provided all conditions of the Small Purchase Procedures Manual (NIH Manual Handbook 2600–103–26.9) are met. Authorized investigators are reminded that: the dollar limit for radioisotopes is $500 and for radionuclides being used under the NIH Broad License delivery must be made within ten (10) days to: *Radiation Safety Officer, National Institutes of Health, Building 21, Radioisotope Laboratory, Bethesda, Maryland 20014.* See Small Purchase Procedures Manual for step-by-step instructions for obtaining radioisotopes by TCO and for list of TCO Account Suppliers.

5. Purchase orders exceeding $500 will be requisitioned in the usual manner by using Form PHS–402–1, "Requisition for Equipment and Sup-

plies," which shall be clearly labeled *"Radioisotope Order."* The requisition must be completed in all normal respects and, in addition, specify that delivery be made to the *Radiation Safety Officer, National Institutes of Health, Building 21, Radioisotope Laboratory, Bethesda, Maryland 20014.* The requisition and accompanying Form NIH–88 are routed through Radiation Safety, Bldg. 21, to the Procurement Section, Bldg. 13.

6. The purchase order will then be prepared by the Procurement Section, Materiel Management, and routed through the Radiation Safety office for final approval. The Radiation Safety Officer will indicate approval and place the AEC license number on the purchase order and forward it to the supplier.



7. The Radiation Safety office will be the receiving point on the NIH reservation for such material and will make the actual delivery to the ordering investigator. Any changes in the original shipping instructions should be furnished this office by the investigator or the Institute ordering office serving him. Shipping information received from the supplier by the Procurement Section and the Receiving Control Reports Section, Bldg. 13, will be furnished immediately to the Radiation Safety office which in turn will keep the ordering investigator properly informed.

8. In the case of ionizing radiation producing machines such as x-ray units, Van de Graaff generators, etc., the notification is made on Form NIH–1912, "Request for Authorization to Purchase and Use Radiation Producing Machinery or Equipment". The filing of Training and Experience Form NIH–465 may or may not be required by the Radiation Committee depending on the device(s), its complexity and the proposed uses. Consult with the Radiation Safety Officer concerning this Training and Experience requirement. The equipment is then requisitioned in the usual manner using Form PHS–402–1.

Shipping Radioactive Materials

1. When radioactive material is to be shipped from NIH, the shipper must notify the Radiation Safety office instead of the Shipping and Receiving Section. The Radiation Safety staff will pick up these shipments on telephone request. The usual NIH shipping request Form NIH 1884 is to be prepared and will accompany the container. Under item 7 of this form the description of articles must include radionuclide, chemical form, and activity (in μCi or mCi).

2. The recipient of any material to be shipped from NIH must provide evidence of an AEC (or agreement state*) license by furnishing a copy of his license to the Radiation Safety office before shipment can be made. Noncompliance with this requirement is a violation of the Atomic Energy Act and is subject to criminal prosecution as well as denial to NIH of further AEC-controlled radioisotopes. Check first with the Radiation Safety staff by phone to see if the recipient's license is already on file. If not, then request a copy from the recipient in order to fulfill this requirement.

3. The investigator is reminded that the NIH specific license of broad scope *covers only the Bethesda reservation and the Auburn Building.* Materials transported by the investigator to other installations must be transferred to the respective licensees in that area as in paragraph 2 above and in a manner complying with applicable AEC and/or Department of Transportation regulations.

4. When an empty radioisotope container is to be returned to the supplier, the ordering investigator must notify the Radiation Safety office, who will certify that it is free of contamination. The container may then be returned through normal channels. Promptness in returning the container is urged. Conditions of purchase usually require that such containers will be returned within a specified period of time.

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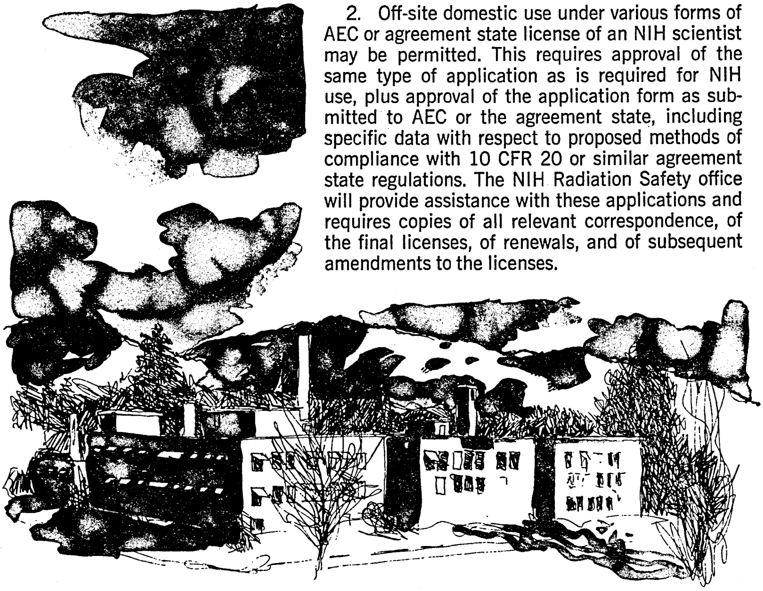
*Agreement States: Those states that have entered into agreements with the AEC for the control of radioactive material.

Off-Site Use of Isotopes by NIH Staff

As specified in NIH Manual Issuance 1344, NIH investigators working with radioactive materials and radiation producing devices will comply with the following:

1. All off-site† uses of radioisotopes, domestic or foreign, under "generally licensed quantities" (10 CFR 31.100) or individual AEC or agreement state license should be subject to the same scientific review and approval by the Radiation Committee as prevails for in-house use.

2. Off-site domestic use under various forms of AEC or agreement state license of an NIH scientist may be permitted. This requires approval of the same type of application as is required for NIH use, plus approval of the application form as submitted to AEC or the agreement state, including specific data with respect to proposed methods of compliance with 10 CFR 20 or similar agreement state regulations. The NIH Radiation Safety office will provide assistance with these applications and requires copies of all relevant correspondence, of the final licenses, of renewals, and of subsequent amendments to the licenses.



3. Off-site foreign use may be authorized following compliance with paragraph (1) and receipt by the Radiation Committee of an acceptable statement indicating the full knowledge and agreement of an appropriate authority in the host country.

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†Off-site: All research locations other than the NIH reservation and the Auburn Building (Bethesda) where NIH personnel are assigned.

4. All NIH scientists using radioisotopes under any circumstances in off-site locations, domestic or foreign, must use NIH personnel monitoring devices when indicated or be under an equivalent monitoring program acceptable to and reporting to the NIH Radiation Safety office.

5. The NIH Radiation Committee and Radiation Safety office are authorized to intervene and apply the applicable NIH regulations to off-site uses of other sources of ionizing radiations employed by NIH personnel.

6. Users of radioisotopes authorized and procured under the NIH Broad AEC License are reminded that this license is specific for the NIH *Bethesda reservation and Auburn Building.* This means that the transfer of radioisotopes from these locations to off-site premises requires clearance through the NIH Radiation Safety office. Transfers of radioisotopes from off-site locations to NIH must be made in accordance with the requirements of "Procurement of Radiation Sources."

GLOSSARY

ABSORBED DOSE: The amount of energy imparted to matter by ionizing radiation per unit mass of irradiated material. (See Rad)

ABSORPTION: The phenomenon by which radiation imparts some or all of its energy to any material through which it passes.

ACTIVITY: The number of nuclear disintegrations occurring in a given quantity of material per unit time. (See Curie)

ALPHA PARTICLE: A strongly ionizing particle emitted from the nucleus during radioactive decay having a mass and charge equal in magnitude to a helium nucleus, consisting of 2 protons and 2 neutrons with a double positive charge.

ALPHA RAY: A stream of fast-moving helium nuclei (alpha particles), a strongly ionizing and weakly penetrating radiation.

ANNIHILATION (Electron): An interaction between a positive and negative electron; their energy, including rest energy, being converted into electromagnetic radiation (annihilation radiation).

ATOM: Smallest particle of an element which is capable of entering into a chemical reaction.

AUTORADIOGRAPH: Record of radiation from radioactive material in an object, made by placing the object in close proximity to a photographic emulsion.

BACKGROUND RADIATION: Ionizing radiation arising from radioactive material other than the one directly under consideration. Background radiation due to cosmic rays and natural radioactivity is always present. There may also be background radiation due to the presence of radioactive substances in other parts of the building, in the building material itself, etc.

BETA PARTICLE: Charged particle emitted from the nucleus of an atom, having a mass and charge equal in magnitude to that of the electron.

BETA RAY: A stream of high speed electrons or positrons of nuclear origin more penetrating but less ionizing than alpha rays.

BREMSSTRAHLUNG: Electromagnetic (x-ray) radiation associated with the deceleration of charged particles passing through matter. Usually associated with energetic beta emitters, e.g., phosphorus-32.

CALIBRATION: Determination of variation from standard, or accuracy, of a measuring instrument to ascertain necessary correction factors.

CONTAMINATION, RADIOACTIVE: Deposition of radioactive material in any place where it is not desired, and particularly in any place where its presence may be harmful. The harm may be in vitiating the validity of an experiment or a procedure, or in actually being a source of excessive exposure to personnel.

CARRIER FREE: An adjective applied to one or more radioactive iostopes of an element in minute quantity, essentially undiluted with stable isotope carrier.

COUNT (Radiation Measurements): The external indication of a device designed to enumerate ionizing events. It may refer to a single detected event or to the total registered in a given period of time. The term is often erroneously used to designate a disintegration, ionizing event, or voltage pulse.

CRITICAL ORGAN: That organ or tissue, the irradiation of which will result in the greatest hazard to the health of the individual or his descendants.

CURIE: The quantity of any radioactive material in which the number of disintegrations is 3.700×10^{10} per second. Abbrevated Ci.

> Millicurie: One-thousandth of a curie (3.7×10^{7} disintegrations per second). Abbreviated mCi. Microcurie: One millionth of a curie (3.7×10^{4} disintegrations per second). Abbreviated μCi. Picocurie: One millionth of a microcurie (3.7×10^{-2} disintegrations per second or 2.22 disintegrations per minute). Abbreviated pCi.

DECAY, RADIOACTIVE: Disintegration of the nucleus of an unstable nuclide by the spontaneous emission of charged particles and/or photons.

DOSE: A general term denoting the quantity of radiation or energy absorbed in a specified mass. For special purposes it must be appropriately qualified, e.g., absorbed dose.

DOSE, ABSORBED: The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The unit of absorbed dose is the rad, which is 100 ergs/gram.

DOSE EQUIVALENT: A quantity used in radiation protection expressing all radiation on a common scale for calculating the effective absorbed dose. The unit of dose equivalent is the rem, which is numerically equal to the absorbed dose in rads multiplied by certain modifying factors such as the quality factor, the distribution factor, etc.

EFFICIENCY (Counters): A measure of the probability that a count will be recorded when radiation is incident on a detector. Usage varies considerably so it is well to make sure which factors (window, transmission, sensitive volume, energy dependence, etc.) are included in a given case.

ELECTRON: Negatively charged elementary particle which is a constituent of every neutral atom. Its unit of negative electricity equals 4.8×10^{-10} electrostatic units or 1.6×10^{-19} coulombs. Its mass is 0.00549 atomic mass units.

ELECTRON CAPTURE: A mode of radioactive decay involving the capture of an orbital electron by its nucleus. Capture from the particular electron shell is designated as "K-electron capture," "L-electron capture," etc.

ELECTRON VOLT: A unit of energy equivalent to the amount of energy gained by an electron in passing through a potential difference of 1 volt. Abbreviated eV. Larger multiple units of the electron volt frequently used are: keV for thousand or kiloelectron volts, MeV for million electron volts and BeV for billion electron volts.

EXPOSURE: A measure of the ionization produced in air by x or gamma radiation. It is the sum of the electrical charges on all ions of one sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air, divided by the mass of air in the volume element. The special unit of exposure is the roentgen.

FILM BADGE: A packet of photographic film used for the approximate measurement of radiation exposure for personnel monitoring purposes. The badge may contain two or more films of differing sensitivity, and it may contain filters which shield parts of the film from certain types of radiation.

FILTER (Radiology), PRIMARY: A sheet of material, usually metal, placed in a beam of radiation to remove, as far as possible, the less penetrating components of the beam. **SECONDARY:** A sheet of material of lower atomic number, relative to that of the primary filter, placed in the filtered beam of radiation to remove characteristic radiation produced by the primary filter.

GAMMA RAY: Very penerating electromagnetic radiation of nuclear origin. Except for origin, identical to x-ray.

GEIGER-MUELLER (G-M) COUNTER: Highly sensitive gas-filled detector and associated circuitry used for radiation detection and measurement.

GENETIC EFFECT OF RADIATION: Inheritable changes, chiefly mutations, produced by the absorption of ionizing radiations. On the basis of present knowledge these effects are purely additive, and there is no recovery.

HALF-LIFE, BIOLOGICAL: The time required for the body to eliminate one-half of an administered dose of any substance by the regular processes of elimination. This time is approximately the same for both stable and radioactive isotopes of a particular element.

HALF-LIFE, EFFECTIVE: Time required for a radioactive nuclide in a system to be diminished 50 percent as a result of the combined action of radioactive decay and biological elimination.

$$\text{Effective half-life} = \frac{\text{Biological half-life} \times \text{Radioactive half-life}}{\text{Biological half-life} + \text{Radioactive half-life}}$$

HALF-LIFE, RADIOACTIVE: Time required for a radioactive substance to lose 50 percent of its activity by decay. Each radionuclide has a unique half-life.

HALF VALUE LAYER (Half thickness): The thickness of any specified material necessary to reduce the intensity of an x-ray or gamma ray beam to one-half its original value.

HEALTH PHYSICS: A term in common use for that branch of radiological science dealing with the protection of personnel from harmful effects of ionizing radiation.

INVERSE SQUARE LAW: The intensity of radiation at any distance from a point source varies inversely as the square of that distance. For example: If the radiation exposure is 100 R/hr at 1 inch from a source, the exposure will be 0.01 R/hr at 100 inches.

ION: Atomic particle, atom, or chemical radical bearing an electrical charge, either negative or positive.

IONIZATION: The process by which a neutral atom or molecule acquires either a positive or a negative charge.

IONIZATION CHAMBER: An instrument designed to measure the quantity of ionizing radiation in terms of the charge of electricity associated with ions produced within a defined volume.

IONIZATION, SPECIFIC: The number of ion pairs per unit length of path of ionizing radiation in a medium; e.g., per centimeter of air or per micron of tissue.

IONIZING RADIATION: Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter.

ISOTOPES: Nuclides having the same number of protons in their nuclei, and hence having the same atomic number, but differing in the number of neutrons, and therefore in the mass number. Almost identical chemical properties exist between isotopes of a particular element.

LABELED COMPOUND: A compound consisting, in part, of labeled molecules. By observations of radioactivity or isotopic composition this compound or it fragments may be followed through physical, chemical or biological processes.

MAXIMUM PERMISSIBLE DOSE (MPD): Maximum dose of radiation which may be received by persons working with ionizing radiation, which will produce no detectable damage over the normal life span.

MILLIROENTGEN (mR): A submultiple of the roentgen equal to one one-thousandth (1/1000th) of a roentgen. (See Roentgen)

MONITORING, RADIOLOGICAL: Periodic or continuous determination of the amount of ionizing radiation or radioactive contamination present in an occupied region as a safety measure for purposes of health protection.

Area Monitoring: Routine monitoring of the level of radiation or of radioactive contamination of any particular area, building, room or equipment.

Personnel Monitoring: Monitoring any part of an individual, his breath, excretions, or any part of his clothing. (See Radiological Survey)

NEUTRON: Elementary particle with a mass approximately the same as that of a hydrogen atom and electrically neutral. It has a half-life in minutes and decays in a free state into a proton and an electron.

NUCLIDE: A species of atom characterized by its mass number, atomic number, and energy state of its nucleus, provided that the atom is capable of existing for a measurable time.

PROTECTIVE BARRIERS: Barriers of radiation absorbing material, such as lead, concrete, plaster, and plastic, that are used to reduce radiation exposure.

Protective Barriers, Primary: Barriers sufficient to attenuate the useful beam to the required degree.

Protective Barriers, Secondary: Barriers sufficient to attenuate stray or scattered radiation to the required degee.

RADIATION: 1. The emission and propagation of energy through space or through a material medium in the form of waves; for instance, the emission and propagation of electromagnetic waves, or of sound and elastic waves. 2. The energy propagated through a material medium as waves; for example, energy in the form of electromagnetic waves or of elastic waves. The term "radiation" or "radiant energy," when unqualified, usually refers to electromagnetic radiation. Such radiation commonly is classified according to frequency as Hertzian, infrared, visible (light), ultra-violet, x-ray, and gamma ray. 3. By extension, corpuscular emissions, such as alpha and beta radiation, or rays of mixed or unknown type, as cosmic radiation.

RADIOLOGICAL SURVEY: Evaluation of the radiation hazards incident to the production, use or existence of radioactive materials or other sources of radiation under a specific set of conditions. Such evaluation customarily includes a physical survey of the disposition of materials and equipment, measurements or estimates of the levels of radiation that may be involved, and a sufficient knowledge of processes using or affecting these materials to predict hazards resulting from expected or possible changes in materials or equipment.

RADIOTOXICITY: Term referring to the potential of an isotope to cause damage to living tissue by absorption of energy from the disintegration of the radioactive material introduced into the body.

RELATIVE BIOLOGICAL EFFECTIVENESS (RBE): For a particular living organism or part of an organism, the ratio of the absorbed dose of a reference radiation that produces a specified biological effect to the absorbed dose of the radiation of interest that produces the same biological effect.

REM: The special unit of dose equivalent. The dose equivalent in rems is numerically equal to the absorbed dose in rads multiplied by the quality factor, distribution factor, and any other necessary modifying factors.

ROENTGEN (R): The quantity of x or gamma radiation such that the associated corpuscular emission per 0.001293 grams of dry air produces, in air, ions carrying one electrostatic unit of quantity of electricity of either sign. The roentgen is the special unit of exposure.

SCINTILLATION COUNTER: A counter in which light flashes produced in a scintillator by ionizing radiation are converted into electrical pulses by a photomultiplier tube.

SHIELDING MATERIAL: Any material which is used to absorb radiation and thus effectively reduce the intensity of radiation, and in some cases eliminate it. Lead, concrete, aluminum, water, and plastic are examples of commonly used shielding material.

SMEAR (Smear or Swipe Test): A procedure in which a swab, e.g., a circle of filter paper, is rubbed on a surface and its radioactivity measured to determine if the surface is contaminated with loose radioactive material.

SPECIFIC ACTIVITY: Total radioactivity of a given nuclide per gram of a compound, element or radioactive nuclide.

TRACER, ISOTOPIC: The isotope or nonnatural mixture of isotopes of an element which may be incorporated into a sample to make possible observation of the course of that element, alone or in combination, through a chemical, biological, or physical process. The observations may be made by measurement of radioactivity or of isotopic abundance.

THERMOLUMINESCENT DOSIMETER: A dosimeter made of certain crystalline material which is capable of both storing a fraction of absorbed ionizing radiation and releasing this energy in the form of visible photons when heated. The amount of light released can be used as a measure of radiation exposure to these crystals.

X-RAYS: Penetrating electromagnetic radiations having wave lengths shorter than those of visible light. They are usually produced by bombarding a metallic target with fast electrons in a high vacuum. In nuclear reactions it is customary to refer to photons originating in the nucleus as gamma rays, and those originating in the extranuclear part of the atom as x-rays. These rays are sometimes called roentgen rays after their discoverer, W. C. Roentgen.

GUIDELINES FOR MAXIMUM PERMISSIBLE DOSES FOR NIH PERSONNEL

Organ	Dose in mrem			
	Year	Quarter	Month	Week
Whole Body (Including Gonads, Lens of Eye, Red Bone Marrow)	5,000	1,250	400	100
Forearms, Hands, Feet and Ankles	75,000	18,750	6,250	1,500
Skin of Whole Body	30,000	7,500	2,500	650
Pregnant Women or Employees Under 18 Years of Age	500	125	40	10

For information on specific organs or tissues not listed, consult with Radiation Committee or Radiation Safety Officer.

CLASSIFICATION OF ISOTOPES ACCORDING TO RELATIVE RADIOTOXICITY PER UNIT ACTIVITY

(Based on Published Data and NIH User Experience)

Class 1 (very high toxicity)

Sr-90 + Y-90, *Pb-210 + Bi-210(Ra D + E), Po-210, At-211, *Ra-226 + 55% *daughter products, Ac-227, *U-233, Pu-239, *Am-241, Cm-242, plus other transuranium isotopes.

Class 2 (high toxicity)

Ca-45, *Ca-47, *Fe-59, *Sr-85, Sr-89, Y-91, *Ru-106 + Rh-106, *I-125, *I-131, *Ba-140 + *La-140, Ce-144 + *Pr-144, Sm-151, *Eu-154, *Tm-170, *Hg-203, *Th-234 + *Pa-234, *natural uranium.

Class 3 (moderate toxicity)

*Na-22, *Na-24, P-32, P-33, S-35, Cl-36, *K-42, *Sc-46, *Sc-47, *Sc-48, *V-48, *Mn-52, *Mn-54, *Mn-56, Fe-55, *Co-57, *Co-58, *Co-60, Ni-59, *Cu-64, *Cu-67, *Zn-65, *Ga-67, *Ga-72, *As-74, *As-76, *Br-82, *Kr-85, *Rb-84, *Rb-86, *Zr-95 + *Nb-95, *Nb-95, *Mo-99, Tc-98, *Rh-105, Pd-103 + Rh-103, *Ag-105, *Ag-111, Cd-109 + *Ag-109, *Sn-113, *Te-127, *Te-129, *I-132, *Xe-133, *Cs-137 + *Ba-137, *La-140, Pr-143, Pm-147, *Ho-166, *Lu-177, *Ta-182, *W-181, *Re-183, Ir-190, *Ir-192, Pt-191, *Pt-193, *Au-196, *Au-198, *Au-199, Tl-200, Tl-202, Tl-204, *Pb-203, *Hg-197.

Class 4 (slight toxicity)

H-3, Be-7, C-14, *F-18, *Cr-51, Ge-71, *Sr-87m, *Tc-99m, *Tl-201.

*Gamma emitter and/or associated photon emitter.

GUIDELINES FOR MAXIMUM ACTIVITIES IN NIH LABORATORIES

Radiotoxicity of Isotopes	Minimum Significant Quantity Utilized	Typical NIH Laboratory	Isotope Laboratory Building 21 (1)
Very high	0.1 μCi	10 μCi or less	10 μCi–10 mCi
High	1.0 μCi	100 μCi or less	100 μCi–100 mCi
Moderate	10 μCi	1 mCi or less	1 mCi–1 Ci
Slight	100 μCi	10 mCi or less	10 mCi–10 Ci

Modifying factors should be applied to the quantities indicated in the last 2 columns of the above table, according to the complexity of the procedures to be followed. The following factors are suggested but due regard should be paid to the circumstances affecting individual cases.

Procedure	*Modifying factor*
Storage (stock solutions)	× 100
Very simple wet operations	× 10
Normal chemical operations	× 1
Complex wet operations with risk of spills	× 0.1
Simple dry operations	× 0.1
Dry and dusty operations	× 0.01

(1) With proper documentation of experimental protocol and with approval of the Radiation Committee, investigators may be permitted to use these quantities in NIH laboratories outside Building 21. With similar documentation, activities exceeding these maximum quantities may be approved for use in Building 21 only.

SELECTED PROPERTIES OF MOST FREQUENTLY ORDERED RADIONUCLIDES

Nuclide	Maximum Beta Energy (MeV)	Gamma Energy (MeV)	Iγ mR/hr/mCi at 1 m	MPBB (μCi)	Critical Organ	Half-Life	
						Radioactive	Biological (days)
^{3}H	0.0186			1000	Body Tissue	12.26y	12
^{14}C	0.156			300	Fat	5730y	12
^{24}Na	1.389	1.369 (100%) 2.754 (100%)	1.84	7	Total Body	14.96h	11
^{32}P	1.710			6	Bone	14.28d	1155
^{33}P	0.248			40	Bone	24.4d	1155
^{35}S	0.167			90	Testis	87.9d	623
^{51}Cr		0.32(9%)	0.016	800	Total Body	27.8d	616
^{125}I		28 keV average (143%)	0.07	1.6	Thyroid	60.2d	138
^{131}I	0.606	0.637 (6.8%) 0.364 (82%)	0.22	0.7	Thyroid	8.05d	138

Column (4), Iγ Milliroentgens per hour at 1 meter from 1 millicurie.

Column (5), Maximum Permissible Body Burden (MPBB). The amount of the isotope maintained in the body which will deliver the maximum permissible dose equivalent rate to the limiting organ. The value given is for material that has been absorbed by the blood stream and deposited in the body. The lung or gastrointestinal tract may be more limiting for continued exposure to chemical forms that are not readily absorbed.

Column (6), Critical Organ. The organ that receives the highest dose equivalent relative to its maximum permissible dose equivalent from a sustained intake (see discussion of Column 5). The maximum permissible body burden may be identical for several organs. Then, the organ with the smallest maximum permissible dose equivalent or the organ affected by most other radioactive materials was chosen.

Column (7), Radioactive Half-Life. Present best value, obtained from "Table of Isotopes—6th Edition" by C. M. Lederer, J. M. Hollander, and I. Perlman, John Wiley & Sons, New York, 1967. The abbreviations used here are: s, second; m, minute; h, hour; d, day; and y, year.

Column (8), Biological Half-Life. The time required for one-half of the stable element to be removed from the critical organ by biological processes, as listed by the ICRP. The actual half-time of elimination depends also on the half-life of the isotope. The "effective half-life" in the critical organ (T_{Eff}) is given by $T_{Eff} = \frac{T_R T_B}{T_R + T_B}$ where T_R is the radioactive half-life and T_B is the biological half-life.

Rules of Thumb

Beta Particles

a. Beta particles of at least 70 keV energy are required to penetrate the nominal protective layer of the skin (7 mg/cm^2 or 0.07 mm).

b. The average energy of a beta-ray spectrum is approximately one-third the maximum energy.

c. The range of beta particles in air is $\sim$ 12 ft/MeV. (Maximum range of ^{32}P beta is 1.71 MeV $\times$ 12 ft/Mev $\cong$ 20 ft).

d. The dose rate in rads per hour in a solution by a beta emitter is $1.12\ EC/\rho$, where E is the average beta energy per disintegration in MeV, C is the concentration in microcuries per cubic centimeter, and ρ is the density of the medium in grams per cubic centimeter. The dose rate at the surface of the solution is one-half the value given by this relation. (For ^{32}P average energy of approximately 0.7 MeV, the dose rate from 1 μCi/cm^3 (in water) is 1.48 rads/hr).

e. The surface dose rate through the nominal protective layer of skin (7 mg/cm^2) from a uniform thin deposition of 1 μCi/cm^2 is about 9 rads/hour for energies above about 0.6 MeV. Note that in a thin layer, the beta dose rate exceeds the gamma dose rate, for equal energies released, by about a factor of 100.

f. For a point source of beta radiation (neglecting self and air absorption) of strength mCi millicuries, the dose rate at 1 cm is approximately equal to 200 $\times$ mCi rads/hour and varies only slowly with beta energy. Dose rate for 1 mCi ^{32}P at 1 cm is approximately 200 rads/hour.

Gamma Rays

a. For a point source gamma emitter with energies between 0.07 and 4 MeV, the exposure rate (mR/hr) within ± 20% at 1 foot is 6 × mCi × E × n, where mCi is the number of millicuries; E, the energy in MeV; and n, the number of gammas per disintegration.

b. The dose rate to tissue in rads per hour in an infinite medium uniformly contaminated by a gamma emitter is 2.12 EC/ρ, where C is the number of microcuries per cubic centimeter, E is the average gamma energy per disintegration in MeV, and ρ is the density of the medium. At the surface of a large body, the dose rate is about half of this.

X-Ray

a. The exposure rate at 2 feet from diagnostic x-ray equipment operated at 100 kVp and 100 milliamperes is approximately 2.3 roentgens/second.

b. Exposure rate at the fluoroscopy table with tube potential at 80 kVp and tube current of 1 milliampere should not exceed 2.1 roentgens/minute.

c. Scattered radiation can be as penetrating as the primary beam.

X-Ray Diffraction

a. The x-ray beam intensities from the primary beam can be as much as 400,000 R/min.

b. Scattered radiation 10 cm from the points of scatter about the x-ray tube head has been measured in the order of 150 R/hr.

c. The threshold dose sufficient to produce skin erythema is 300 to 400 roentgens.

d. The minimum cataractogenic single dose is 200 rads, while a dose of 750 rads exhibits a high incidence of cataract formation.

Miscellaneous

a. The activity of any radionuclide is reduced to less than 1% after 7 half-lives (i.e., 2^{-7} = 0.8%).

b. For material with a half-life greater than six days, the change in activity in 24 hours will be less than 10%.

MIRD Absorbed Dose Calculations

The following are examples of the equations and calculations necessary to estimate absorbed dose according to the schema developed and published by the Medical Internal Radiation Dose (MIRD) Committee of the Society of Nuclear Medicine. Pamphlets containing the required data may be obtained by writing: MIRD Committee, Society of Nuclear Medicine, 211 E. 43rd Street, New York, New York 10017. A limited number of copies are available for short term loan from the Radiation Safety office. Reminder: when using the MIRD method, it is most important to keep all quantities in the specified units.

A. General Equation

$$\bar{D}(v_2 \leftarrow v_1) = \frac{\tilde{A}}{m} \sum_i \Delta_i \phi_i (v_2 \leftarrow v_1)$$

where $\bar{D}$ = mean absorbed dose (rads)
$(v_2 \leftarrow v_1)$ = target volume (v_2) absorbing radiation from source volume (v_1)
$\tilde{A}$ = cumulated activity (μCi-h)
m = mass of target organ (g)
Δ = equilibrium dose constant (g-rad/μCi-h)
i = subscript symbol for all types of radiation
ϕ = absorbed fraction (dimensionless)

B. Other Important Equations

1. $\tilde{A} = A_0 \int_{t_0}^{t} \exp(-0.693t/T_{eff})\, dt$

where A_0 = initial activity in source volume (μCi)
t = time (h)
T_{eff} = effective half-life (h)

2. $\frac{1}{T_{eff}} = \frac{1}{T_{bio}} + \frac{1}{T_{phy}}$

where T_{bio} = biological half-life (h) of isotope in the source volume
T_{phy} = physical half-life (h)

3. For complete disintegration of the isotope:
$\tilde{A} = A_0\,(1.44 \times T_{eff})$

4. For non-pentrating radiation:
$\phi_{n-p}(v_1 \longleftrightarrow v_1) = 1$
$\phi_{n-p}(v_2 \leftarrow v_1) = 0$, if $v_2 \neq v_1$
where $_{n-p}$ = the subscript indicating non-penetrating radiations
$(v_1 \longleftrightarrow v_1)$ = target organ and source are the same volumes

5. For penetrating radiation:
ϕ is dependent upon the geometry of the system and energies of the radiation(s) and can be found in MIRD Pamphlet 5. If necessary, plot values of ϕ for specific source and target organs vs. energy.

C. Specific Example

The following example is given solely to demonstrate the method of calculation and does not necessarily indicate that the target organs selected will receive the highest absorbed doses.

Example: 0.1 mCi ^{24}Na is administered orally and is excreted exponentially from the stomach with a three hour half-time. What is the absorbed dose to the stomach? to the total body? (Simplifying assumption: idealized condition with no absorption of ^{24}Na from the stomach into the body.)

1. Necessary Information on ^{24}Na in the Stomach
   a. Biological half-life (T_{bio}) = 3 h (given)
   b. Physical half-life (T_{phy}) = 15 h (from MIRD Pamphlet 4, p. 16)
   c. Calculated effective half-life:

$$\frac{1}{T_{eff}} = \frac{1}{3} + \frac{1}{15};\ T_{eff} = 2.5\text{ h}$$

   d. Decay data (from MIRD Pamphlet 4, p. 16)

Radiation Type	Energy (MeV)	Δ_i $\left[\frac{\text{g-rad}}{\mu\text{Ci-h}}\right]$
Beta-1	0.5547	1.1803
Gamma-1	1.3685	2.9149
Gamma-2	2.7539	5.8599

   e. Biological data (from MIRD Pamphlet 5, Table 1, p. 8)
      1) Source organ: stomach, 402 g
      2) Target organ: stomach, 402 g
      3) Target organ: total body, 70,036 g

2. Calculation of Dose from Stomach (v_1) to Stomach (v_1)
   a. Calculation of $\sum_i \Delta_i\phi_i$
      1) Non-penetrating radiation

$\phi_{n-p}(v_1 \longleftrightarrow v_1) = 1$

$\sum_{n-p}\Delta\phi = 1 \times 1.1803 = 1.1803$ g-rad/μCi-h

      2) Penetrating radiation

Values of ϕ for penetrating radiation are given in MIRD Pamphlet 5, p. 19.

$\phi_{\gamma_1} = 0.09$

$\phi_{\gamma_2} = 0.072$

$\sum\Delta_{\gamma_1}\phi_{\gamma_1} = 2.9149 \times 0.09 = 0.2623$

$\sum\Delta_{\gamma_2}\phi_{\gamma_2} = 5.8599 \times 0.072 = 0.4219$

$\sum_p\Delta\phi = 0.2623 + 0.4219 = 0.6842$ g-rad/μCi-h

      3) Total $\sum\Delta\phi$

$\sum_{n-p}\Delta\phi + \sum_p\Delta\phi = 1.1803 + 0.6842 = 1.8645$ g-rad/μCi-h

b. Calculation of Cumulated Activity

$\tilde{A} = A_o(1.44 \times T_{eff}) = 100(1.44 \times 2.5) = 360\ \mu\text{Ci-h}$

c. Calculation of Dose to the Stomach from Source in the Stomach

$$\bar{D} = \frac{\tilde{A}}{m}\sum_i \Delta_i\phi_i = \frac{360\ \mu\text{Ci-h}}{402\ \text{g}} \times 1.8645\ \frac{\text{g-rad}}{\mu\text{Ci-h}} = 1.669\ \text{rads}$$

3. Calculation of Dose from the Stomach (v_1) to the Total Body (v_2)

a. Calculation of $\sum_i \Delta_i\phi_i$

1) Non-penetrating radiation

$\phi_{n-p}\ (v_2 \leftarrow v_1) = 0$; thus, no contribution to absorbed dose to total body

2) Penetrating radiation

Values of ϕ for penetrating radiation are given in MIRD Pamphlet 5, p. 19.

$\phi_{\gamma_1} = 0.37$

$\phi_{\gamma_2} = 0.33$

$\sum \Delta_{\gamma_1}\phi_{\gamma_1} = 2.9149 \times 0.37 = 1.0785$

$\sum \Delta_{\gamma_2}\phi_{\gamma_2} = 5.8599 \times 0.33 = 1.9338$

$\sum_p \Delta\phi = 1.0785 + 1.9338 = 3.0122$ g-rad/μCi-h

3) Total $\sum \Delta\phi$

$\sum_{n-p} \Delta\phi + \sum_p \Delta\phi = 0 + 3.0122 = 3.0122$ g-rad/μCi-h

b. Calculation of Cumulated Activity

Same as above: 360 μCi-h.

c. Calculation of Dose to the Total Body from the Stomach

$$\bar{D} = \frac{\tilde{A}}{m}\sum_i \Delta_i\phi_i = \frac{360\ \mu\text{Ci--h}}{70{,}036\ \text{g}} \times 3.0122\ \frac{\text{g--rad}}{\mu\text{Ci--h}} = 0.015\ \text{rads}$$

4. Summary of Dose Calculations

100 μCi ^{24}Na; Source Organ: Stomach

Target Organ	Absorbed Dose (rads)
Stomach	1.669
Total Body	0.015

Selected Decay Corrections

Calcium – 45

165 Days

Days	Days									
	0	2	4	6	8	10	12	14	16	18
0	1.0000	.9916	.9833	.9751	.9670	.9589	.9508	.9429	.9350	.9272
20	.9194	.9117	.9041	.8965	.8890	.8816	.8742	.8669	.8596	.8525
40	.8453	.8383	.8312	.8243	.8174	.8105	.8038	.7970	.7904	.7838
60	.7772	.7707	.7643	.7579	.7515	.7452	.7390	.7328	.7267	.7206
80	.7146	.7086	.7027	.6968	.6910	.6852	.6794	.6738	.6681	.6625
100	.6570	.6515	.6460	.6406	.6353	.6300	.6247	.6195	.6143	.6091
120	.6040	.5990	.5940	.5890	.5841	.5792	.5743	.5695	.5648	.5601
140	.5554	.5507	.5461	.5415	.5370	.5325	.5281	.5236	.5193	.5149
160	.5106	.5063	.5021	.4979	.4937	.4896	.4855	.4814	.4774	.4734
180	.4695	.4655	.4616	.4578	.4540	.4502	.4464	.4427	.4389	.4353
200	.4316	.4280	.4244	.4209	.4174	.4139	.4104	.4070	.4036	.4002
220	.3969	.3935	.3902	.3870	.3837	.3805	.3773	.3742	.3711	.3679
240	.3649	.3618	.3588	.3558	.3528	.3499	.3469	.3440	.3412	.3383
260	.3355	.3327	.3299	.3271	.3244	.3217	.3190	.3163	.3137	.3110
280	.3084	.3059	.3033	.3008	.2982	.2957	.2933	.2908	.2884	.2860
300	.2836	.2812	.2789	.2765	.2742	.2719	.2696	.2674	.2651	.2629
320	.2607	.2585	.2564	.2542	.2521	.2500	.2479	.2458	.2438	.2417
340	.2397	.2377	.2357	.2337	.2318	.2299	.2279	.2260	.2241	.2223
360	.2204	.2186	.2167	.2149	.2131	.2113	.2096	.2078	.2061	.2043

Calcium – 47

4.54 Days

Days	Hours											
	0	1	2	3	4	5	6	7	8	9	10	11
0.0	1.0000	.9937	.9874	.9811	.9749	.9687	.9626	.9564	.9504	.9444	.9384	.9324
0.5	.9265	.9206	.9148	.9090	.9032	.8975	.8918	.8862	.8805	.8749	.8694	.8639
1.0	.8584	.8530	.8476	.8422	.8368	.8315	.8263	.8210	.8158	.8106	.8055	.8004
1.5	.7953	.7903	.7853	.7803	.7753	.7704	.7655	.7607	.7559	.7511	.7463	.7416
2.0	.7369	.7322	.7275	.7229	.7184	.7138	.7093	.7048	.7003	.6959	.6914	.6871
2.5	.6827	.6784	.6741	.6698	.6656	.6613	.6571	.6530	.6488	.6447	.6406	.6366
3.0	.6325	.6285	.6245	.6206	.6166	.6127	.6088	.6050	.6011	.5973	.5935	.5898
3.5	.5860	.5823	.5786	.5750	.5713	.5677	.5641	.5605	.5570	.5534	.5499	.5464
4.0	.5430	.5395	.5361	.5327	.5293	.5260	.5226	.5193	.5160	.5128	.5095	.5063
4.5	.5031	.4999	.4967	.4936	.4904	.4873	.4842	.4812	.4781	.4751	.4721	.4691
5.0	.4661	.4631	.4602	.4573	.4544	.4515	.4486	.4458	.4430	.4402	.4374	.4346
5.5	.4318	.4291	.4264	.4237	.4210	.4183	.4157	.4130	.4104	.4078	.4052	.4026
6.0	.4001	.3976	.3950	.3925	.3900	.3876	.3851	.3827	.3802	.3778	.3754	.3731
6.5	.3707	.3683	.3660	.3637	.3614	.3591	.3568	.3545	.3523	.3501	.3478	.3456
7.0	.3434	.3413	.3391	.3370	.3348	.3327	.3306	.3285	.3264	.3243	.3223	.3202
7.5	.3182	.3162	.3142	.3122	.3102	.3082	.3063	.3043	.3024	.3005	.2986	.2967
8.0	.2948	.2929	.2911	.2892	.2874	.2856	.2838	.2820	.2802	.2784	.2766	.2749
8.5	.2731	.2714	.2697	.2680	.2663	.2646	.2629	.2613	.2596	.2579	.2563	.2547
9.0	.2531	.2515	.2499	.2483	.2467	.2451	.2436	.2421	.2405	.2390	.2375	.2360
9.5	.2345	.2330	.2315	.2300	.2286	.2271	.2257	.2243	.2228	.2214	.2200	.2186
10.0	.2172	.2159	.2145	.2131	.2118	.2104	.2091	.2078	.2065	.2052	.2038	.2026
10.5	.2013	.2000	.1987	.1975	.1962	.1950	.1937	.1925	.1913	.1901	.1889	.1877
11.0	.1865	.1853	.1841	.1830	.1818	.1806	.1795	.1784	.1772	.1761	.1750	.1739
11.5	.1728	.1717	.1706	.1695	.1684	.1674	.1663	.1652	.1642	.1632	.1621	.1611
12.0	.1601	.1591	.1581	.1570	.1561	.1551	.1541	.1531	.1521	.1512	.1502	.1493
12.5	.1483	.1474	.1464	.1455	.1446	.1437	.1428	.1419	.1410	.1401	.1392	.1383
13.0	.1374	.1365	.1357	.1348	.1340	.1331	.1323	.1314	.1306	.1298	.1289	.1281
13.5	.1273	.1265	.1257	.1249	.1241	.1233	.1225	.1218	.1210	.1202	.1195	.1187
14.0	.1180	.1172	.1165	.1157	.1150	.1143	.1135	.1128	.1121	.1114	.1107	.1100
14.5	.1093	.1086	.1079	.1072	.1065	.1059	.1052	.1045	.1039	.1032	.1025	.1019

Chromium – 51

27.8 Days

Days	Hours											
	0	2	4	6	8	10	12	14	16	18	20	22
0	1.0000	.9979	.9959	.9938	.9917	.9897	.9876	.9856	.9835	.9815	.9794	.9774
1	.9754	.9734	.9713	.9693	.9673	.9653	.9633	.9613	.9593	.9573	.9553	.9533
2	.9514	.9494	.9474	.9454	.9435	.9415	.9396	.9376	.9357	.9337	.9318	.9299
3	.9279	.9260	.9241	.9222	.9202	.9183	.9164	.9145	.9126	.9107	.9088	.9070
4	.9051	.9032	.9013	.8995	.8976	.8957	.8939	.8920	.8902	.8883	.8865	.8846
5	.8828	.8810	.8791	.8773	.8755	.8737	.8719	.8700	.8682	.8664	.8646	.8628
6	.8611	.8593	.8575	.8557	.8539	.8522	.8504	.8486	.8469	.8451	.8433	.8416
7	.8398	.8381	.8364	.8346	.8329	.8312	.8294	.8277	.8260	.8243	.8226	.8209
8	.8192	.8175	.8158	.8141	.8124	.8107	.8090	.8073	.8057	.8040	.8023	.8007
9	.7990	.7973	.7957	.7940	.7924	.7907	.7891	.7875	.7858	.7842	.7826	.7809
10	.7793	.7777	.7761	.7745	.7729	.7713	.7697	.7681	.7665	.7649	.7633	.7617
11	.7601	.7586	.7570	.7554	.7538	.7523	.7507	.7492	.7476	.7460	.7445	.7430
12	.7414	.7399	.7383	.7368	.7353	.7337	.7322	.7307	.7292	.7277	.7262	.7247
13	.7232	.7217	.7202	.7187	.7172	.7157	.7142	.7127	.7112	.7098	.7083	.7068
14	.7053	.7039	.7024	.7010	.6995	.6981	.6966	.6952	.6937	.6923	.6908	.6894
15	.6880	.6865	.6851	.6837	.6823	.6809	.6795	.6780	.6766	.6752	.6738	.6724
16	.6710	.6696	.6683	.6669	.6655	.6641	.6627	.6613	.6600	.6586	.6572	.6559
17	.6545	.6532	.6518	.6504	.6491	.6477	.6464	.6451	.6437	.6424	.6411	.6397
18	.6384	.6371	.6357	.6344	.6331	.6318	.6305	.6292	.6279	.6266	.6253	.6240
19	.6227	.6214	.6201	.6188	.6175	.6162	.6150	.6137	.6124	.6111	.6099	.6086
20	.6073	.6061	.6048	.6036	.6023	.6011	.5998	.5986	.5973	.5961	.5949	.5936
21	.5924	.5912	.5899	.5887	.5875	.5863	.5850	.5838	.5826	.5814	.5802	.5790
22	.5778	.5766	.5754	.5742	.5730	.5718	.5706	.5695	.5683	.5671	.5659	.5647
23	.5636	.5624	.5612	.5601	.5589	.5577	.5566	.5554	.5543	.5531	.5520	.5508
24	.5497	.5485	.5474	.5463	.5451	.5440	.5429	.5418	.5406	.5395	.5384	.5373
25	.5362	.5350	.5339	.5328	.5317	.5306	.5295	.5284	.5273	.5262	.5251	.5240
26	.5230	.5219	.5208	.5197	.5186	.5175	.5165	.5154	.5143	.5133	.5122	.5111
27	.5101	.5090	.5080	.5069	.5059	.5048	.5038	.5027	.5017	.5006	.4996	.4985
28	.4975	.4965	.4954	.4944	.4934	.4924	.4913	.4903	.4893	.4883	.4873	.4863
29	.4853	.4843	.4832	.4822	.4812	.4802	.4792	.4783	.4773	.4763	.4753	.4743

Cobalt – 57

270 Days

Days	Days									
	0	2	4	6	8	10	12	14	16	18
0	1.0000	.9949	.9898	.9847	.9797	.9747	.9697	.9647	.9598	.9548
20	.9500	.9451	.9402	.9354	.9306	.9259	.9211	.9164	.9117	.9071
40	.9024	.8978	.8932	.8886	.8841	.8795	.8750	.8706	.8661	.8617
60	.8572	.8529	.8485	.8441	.8398	.8355	.8312	.8270	.8227	.8185
80	.8143	.8102	.8060	.8019	.7978	.7937	.7896	.7856	.7816	.7776
100	.7736	.7696	7657	.7618	.7579	.7540	.7501	.7463	.7425	.7387
120	.7349	.7311	.7274	.7236	.7199	.7162	.7126	.7089	.7053	.7017
140	.6981	.6945	.6910	.6874	.6839	.6804	.6769	.6734	.6700	.6666
160	.6632	.6598	.6564	.6530	.6497	.6463	.6430	.6397	.6365	.6332
180	.6300	.6267	.6235	.6203	.6172	.6140	.6108	.6077	.6046	.6015
200	.5984	.5954	.5923	.5893	.5863	.5833	.5803	.5773	.5743	.5714
220	.5685	.5656	.5627	.5598	.5569	.5541	.5512	.5484	.5456	.5428
240	.5400	.5373	.5345	.5318	.5291	.5263	.5236	.5210	.5183	5156
260	.5130	5104	.5078	.5052	.5026	.5000	.4974	.4949	.4924	.4898
280	.4873	.4848	.4823	.4799	.4774	.4750	.4725	.4701	.4677	.4653
300	.4629	.4606	.4582	.4559	.4535	.4512	.4489	.4466	.4443	.4420
320	.4398	.4375	.4353	.4330	.4308	.4286	.4264	.4242	.4221	.4199
340	.4178	.4156	.4135	.4114	.4093	.4072	.4051	.4030	.4009	.3989
360	.3969	.3948	.3928	.3908	.3888	.3868	.3848	.3828	.3809	.3789
380	.3770	.3751	.3731	.3712	.3693	.3674	.3656	.3637	.3618	.3600
400	.3581	.3563	.3545	.3526	.3508	.3490	.3473	.3455	.3437	.3419
420	.3402	.3385	.3367	.3350	.3333	.3316	.3299	.3282	.3265	.3248
440	.3232	.3215	.3199	.3182	.3166	.3150	.3134	.3118	.3102	.3086
460	.3070	.3054	.3039	.3023	.3008	.2992	.2977	.2962	.2946	.2931
480	.2916	.2901	.2887	.2872	.2857	.2842	.2828	.2813	.2799	.2785

Fluorine – 18

109.7 Minutes

Minutes	Minutes									
	0	1	2	3	4	5	6	7	8	9
0	1.0000	.9937	.9874	.9812	.9750	.9689	.9628	.9567	.9507	.9447
10	.9388	.9329	.9270	.9211	.9153	.9096	.9038	.8982	.8925	.8869
20	.8813	.8757	.8702	.8647	.8593	.8539	.8485	.8432	.8378	.8326
30	.8273	.8221	.8169	.8118	.8067	.8016	.7965	.7915	.7865	.7816
40	.7767	.7718	.7669	.7621	.7573	.7525	.7478	.7431	.7384	.7337
50	.7291	.7245	.7200	.7154	.7109	.7064	.7020	.6976	.6932	.6888
1 Hour	.6845	.6802	.6759	.6716	.6674	.6632	.6590	.6549	.6507	.6466
10	.6426	.6385	.6345	.6305	.6265	.6226	.6187	.6148	.6109	.6070
20	.6032	.5994	.5956	.5919	.5882	.5845	.5808	.5771	.5735	.5699
30	.5663	.5627	.5592	.5556	.5521	.5487	.5452	.5418	.5384	.5350
40	.5316	.5283	.5249	.5216	.5183	.5151	.5118	.5086	.5054	.5022
50	.4991	.4959	.4928	.4897	.4866	.4835	.4805	.4775	.4745	.4715
2 Hours	.4685	.4655	.4626	.4597	.4568	.4539	.4511	.4482	.4454	.4426
10	.4398	.4370	.4343	.4316	.4288	.4261	.4234	.4208	.4181	.4155
20	.4129	.4103	.4077	.4051	.4026	.4000	.3975	.3950	.3925	.3901
30	.3876	.3852	.3827	.3803	.3779	.3755	.3732	.3708	.3685	.3662
40	.3639	.3616	.3593	.3570	.3548	.3525	.3503	.3481	.3459	.3438
50	.3416	.3394	.3373	.3352	.3331	.3310	.3289	.3268	.3247	.3227
3 Hours	.3207	.3187	.3166	.3146	.3127	.3107	.3087	.3068	.3049	.3029
10	.3010	.2991	.2973	.2954	.2935	.2917	.2898	.2880	.2862	.2844
20	.2826	.2808	.2791	.2773	.2755	.2738	.2721	.2704	.2687	.2670
30	.2653	.2636	.2620	.2603	.2587	.2570	.2554	.2538	.2522	.2506
40	.2491	.2475	.2459	.2444	.2428	.2413	.2398	.2383	.2368	.2353
50	.2338	.2323	.2309	.2294	.2280	.2265	.2251	.2237	.2223	.2209
4 Hours	.2195	.2181	.2167	.2154	.2140	.2127	.2113	.2100	.2087	.2074
10	.2060	.2048	.2035	.2022	.2009	.1996	.1984	.1971	.1959	.1947
20	.1934	.1922	.1910	.1898	.1886	.1874	.1862	.1851	.1839	.1827
30	.1816	.1804	.1793	.1782	.1771	.1759	.1748	.1737	.1726	.1715
40	.1705	.1694	.1683	.1673	.1662	.1652	.1641	.1631	.1621	.1610
50	.1600	.1590	.1580	.1570	.1560	.1551	.1541	.1531	.1521	.1512
5 Hours	.1502	.1493	.1483	.1474	.1465	.1456	.1446	.1437	.1428	.1419
10	.1410	.1401	.1393	.1384	.1375	.1366	.1358	.1349	.1341	.1332
20	.1324	.1316	.1307	.1299	.1291	.1283	.1275	.1267	.1259	.1251
30	.1243	.1235	.1227	.1220	.1212	.1204	.1197	.1189	.1182	.1174
40	.1167	.1159	.1152	.1145	.1138	.1131	.1123	.1116	.1109	.1102
50	.1095	.1088	.1082	.1075	.1068	.1061	.1055	.1048	.1041	.1035
6 Hours	.1028	.1022	.1015	.1009	.1003	.0996	.0990	.0984	.0978	.0971

Gallium – 67

77.9 Hours

Hours	Hours											
	0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5
0	1.0000	.9956	.9911	.9867	.9824	.9780	.9737	.9693	.9650	.9608	.9565	.9522
6	.9480	.9438	.9396	.9354	.9313	.9272	.9230	.9189	.9149	.9108	.9068	.9027
12	.8987	.8947	.8908	.8868	.8829	.8790	.8751	.8712	.8673	.8635	.8596	.8558
18	.8520	.8482	.8445	.8407	.8370	.8333	.8296	.8259	.8222	.8186	.8149	.8113
1 Day	.8077	.8041	.8006	.7970	.7935	.7899	.7864	.7829	.7795	.7760	.7726	.7691
6	.7657	.7623	.7589	.7556	.7522	.7489	.7456	.7422	.7389	.7357	.7324	.7291
12	.7259	.7227	.7195	.7163	.7131	.7099	.7068	.7037	.7005	.6974	.6943	.6912
18	.6882	.6851	.6821	.6791	.6760	.6730	.6700	.6671	.6641	.6612	.6582	.6553
2 Days	.6524	.6495	.6466	.6437	.6409	.6380	.6352	.6324	.6296	.6268	.6240	.6212
6	.6185	.6157	.6130	.6103	.6076	.6049	.6022	.5995	.5969	.5942	.5916	.5889
12	.5863	.5837	.5811	.5786	.5760	.5734	.5709	.5684	.5658	.5633	.5608	.5583
18	.5558	.5534	.5509	.5485	.5460	.5436	.5412	.5388	.5364	.5340	.5317	.5293
3 Days	.5270	.5246	.5223	.5200	.5177	.5154	.5131	.5108	.5085	.5063	.5040	.5018
6	.4996	.4973	.4951	.4929	.4907	.4886	.4864	.4842	.4821	.4799	.4778	.4757
12	.4736	.4715	.4694	.4673	.4652	.4632	.4611	.4591	.4570	.4550	.4530	.4510
18	.4490	.4470	.4450	.4430	.4410	.4391	.4371	.4352	.4333	.4313	.4294	.4275
4 Days	.4256	.4237	.4219	.4200	.4181	.4163	.4144	.4126	.4107	.4089	.4071	.4053
6	.4035	.4017	.3999	.3981	.3964	.3946	.3929	.3911	.3894	.3877	.3859	.3842
12	.3825	.3808	.3791	.3774	.3758	.3741	.3724	.3708	.3691	.3675	.3659	.3643
18	.3626	.3610	.3594	.3578	.3562	.3547	.3531	.3515	.3500	.3484	.3469	.3453
5 Days	.3438	.3423	.3407	.3392	.3377	.3362	.3347	.3332	.3318	.3303	.3288	.3274
6	.3259	.3245	.3230	.3216	.3202	.3187	.3173	.3159	.3145	.3131	.3117	.3103
12	.3090	.3076	.3062	.3049	.3035	.3022	.3008	.2995	.2982	.2968	.2955	.2942
18	.2929	.2916	.2903	.2890	.2877	.2865	.2852	.2839	.2827	.2814	.2802	.2789
6 Days	.2777	.2764	.2752	.2740	.2728	.2716	.2704	.2692	.2680	.2668	.2656	.2644
6	.2632	.2621	.2609	.2598	.2586	.2574	.2563	.2552	.2540	.2529	.2518	.2507
12	.2496	.2484	.2473	.2462	.2452	.2441	.2430	.2419	.2408	.2398	.2387	.2376
18	.2366	.2355	.2345	.2334	.2324	.2314	.2304	.2293	.2283	.2273	.2263	.2253
7 Days	.2243	.2233	.2223	.2213	.2203	.2193	.2184	.2174	.2164	.2155	.2145	.2136

Gold – 198

2.697 Days

Hours	Hours											
	0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5
0	1.0000	.9947	.9893	.9841	.9788	.9736	.9684	.9632	.9581	.9530	.9479	.9428
6	.9378	.9328	.9278	.9228	.9179	.9130	.9081	.9033	.8984	.8937	.8889	.8841
12	.8794	.8747	.8700	.8654	.8608	.8562	.8516	.8471	.8425	.8380	.8336	.8291
18	.8247	.8203	.8159	.8115	.8072	.8029	.7986	.7943	.7901	.7859	7817	.7775
1 Day	.7734	.7692	.7651	.7610	.7570	.7529	.7489	.7449	.7409	.7370	.7330	.7291
6	.7252	.7214	.7175	.7137	.7099	.7061	.7023	.6986	.6948	.6911	.6874	.6838
12	.6801	.6765	.6729	.6693	.6657	.6621	.6586	.6551	.6516	.6481	.6446	.6412
18	.6378	.6344	.6310	.6276	.6243	.6209	.6176	.6143	.6110	.6078	.6045	.6013
2 Days	.5981	.5949	.5917	.5886	.5854	.5823	.5792	.5761	.5730	.5700	.5669	.5639.
6	.5609	.5579	.5549	.5519	.5490	.5461	.5431	.5402	.5374	.5345	.5316	.5288
12	.5260	.5232	.5204	.5176	.5148	.5121	.5093	.5066	.5039	.5012	.4985	.4959
18	.4932	.4906	.4880	.4854	.4828	.4802	.4776	.4751	.4726	.4700	.4675	.4650
3 Days	.4625	.4601	.4576	.4552	.4527	.4503	.4479	.4455	.4431	.4408	.4384	.4361
6	.4338	.4314	.4291	.4268	.4246	.4223	.4200	.4178	.4156	.4133	.4111	.4089
12	.4068	.4046	.4024	.4003	.3981	.3960	.3939	.3918	.3897	.3876	.3856	.3835
18	.3815	.3794	.3774	.3754	.3734	.3714	.3694	.3674	.3655	3635	.3616	.3596
4 Days	.3577	.3558	.3539	.3520	.3501	.3483	.3464	.3446	.3427	.3409	.3391	.3373
6	.3355	.3337	.3319	.3301	.3283	.3266	.3248	.3231	.3214	.3197	.3180	.3163
12	.3146	.3129	.3112	.3096	.3079	.3063	.3046	.3030	.3014	.2998	.2982	.2966
18	.2950	.2934	.2919	.2903	.2887	.2872	.2857	.2841	.2826	.2811	.2796	.2781
5 Days	.2766	.2752	.2737	.2722	.2708	.2693	.2679	.2665	.2650	.2636	.2622	.2608
6	.2594	.2580	.2567	.2553	.2539	.2526	.2512	.2499	.2485	.2472	.2459	.2446
12	.2433	.2420	.2407	.2394	.2381	.2369	.2356	.2343	.2331	.2318	.2306	.2294
18	.2281	.2269	.2257	.2245	.2233	.2221	.2209	.2197	.2186	.2174	.2162	.2151
6 Days	.2139	.2128	.2117	.2105	.2094	.2083	.2072	.2061	.2050	.2039	.2028	.2017
6	.2006	.1996	.1985	.1974	.1964	.1953	.1943	.1932	.1922	.1912	.1902	.1892
12	.1881	.1871	.1861	.1851	.1842	.1832	.1822	.1812	.1803	.1793	.1783	.1774
18	.1764	.1755	.1746	.1736	.1727	.1718	.1709	.1699	.1690	.1681	.1672	.1663
7 Days	.1655	.1646	.1637	.1628	.1620	.1611	.1602	.1594	.1585	.1577	.1568	.1560

Hydrogen – 3

12.26 Years

Years	Months											
	0	1	2	3	4	5	6	7	8	9	10	11
0	1.0000	.9953	.9906	.9860	.9813	.9767	.9721	.9676	.9630	.9585	.9540	.9495
1	.9450	.9406	.9362	.9318	.9274	.9230	.9187	.9144	.9101	.9058	.9015	.8973
2	.8931	.8889	.8847	.8805	.8764	.8723	.8682	.8641	.8600	.8560	.8520	.8480
3	.8440	.8400	.8361	.8321	.8282	.8243	.8205	.8166	.8128	.8090	.8052	.8014
4	.7976	.7939	.7901	.7864	.7827	.7790	.7754	.7717	.7681	.7645	.7609	.7573
5	.7538	.7502	.7467	.7432	.7397	.7362	.7327	.7293	.7259	.7225	.7191	.7157
6	.7123	.7090	.7056	.7023	.6990	.6957	.6925	.6892	.6860	.6827	.6795	.6763
7	.6732	.6700	.6669	.6637	.6606	.6575	.6544	.6513	.6483	.6452	.6422	.6392
8	.6362	.6332	.6302	.6272	.6243	.6214	.6184	.6155	.6126	.6098	.6069	.6040
9	.6012	.5984	.5956	.5928	.5900	.5872	.5844	.5817	.5790	.5762	.5735	.5708

Iodine – 125

60.2 Days

Days	Days									
	0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5
0	1.0000	.9943	.9886	.9829	.9772	.9716	.9660	.9605	.9550	.9495
5	.9441	.9386	.9332	.9279	.9226	.9173	.9120	.9068	.9016	.8964
10	.8912	.8861	.8810	.8760	.8710	.8660	.8610	.8560	.8511	.8462
15	.8414	.8366	.8317	.8270	.8222	.8175	.8128	.8081	.8035	.7989
20	.7943	.7898	.7852	.7807	.7762	.7718	.7673	.7629	.7586	.7542
25	.7499	.7456	.7413	.7370	.7328	.7286	.7244	.7203	.7161	.7120
1 Month	.7079	.7039	.6998	.6958	.6918	.6878	.6839	.6800	.6761	.6722
5	.6683	.6645	.6607	.6569	.6531	.6494	.6456	.6419	.6382	.6346
10	.6309	.6273	.6237	.6201	.6166	.6130	.6095	.6060	.6025	.5991
15	.5956	.5922	.5888	.5854	.5821	.5787	.5754	.5721	.5688	.5656
20	.5623	.5591	.5559	.5527	.5495	.5464	.5432	.5401	.5370	.5339
25	.5309	.5278	.5248	.5218	.5188	.5158	.5128	.5099	.5070	.5040
2 Months	.5012	.4983	.4954	.4926	.4897	.4869	.4841	.4814	.4786	.4758
5	.4731	.4704	.4677	.4650	.4623	.4597	.4571	.4544	.4518	.4492
10	.4466	.4441	.4415	.4390	.4365	.4340	.4315	.4290	.4265	.4241
15	.4217	.4192	.4168	.4144	.4121	.4097	.4073	.4050	.4027	.4004
20	.3981	.3958	.3935	.3913	.3890	.3868	.3846	.3823	.3802	.3780
25	.3758	.3736	.3715	.3694	.3672	.3651	.3630	.3610	.3589	.3568
3 Months	.3548	.3527	.3507	.3487	.3467	.3447	.3427	.3408	.3388	.3369
5	.3349	.3330	.3311	.3292	.3273	.3254	.3236	.3217	.3199	.3180
10	.3162	.3144	.3126	.3108	.3090	.3072	.3055	.3037	.3020	.3002
15	.2985	.2968	.2951	.2934	.2917	.2900	.2884	.2867	.2851	.2834
20	.2818	.2802	.2786	.2770	.2754	.2738	.2722	.2707	.2691	.2676
25	.2660	.2645	.2630	.2615	.2600	.2585	.2570	.2555	.2541	.2526
4 Months	.2512	.2497	.2483	.2469	.2454	.2440	.2426	.2412	.2398	.2385

Iodine – 131

8.05 Days

Days	Hours											
	0	1	2	3	4	5	6	7	8	9	10	11
0.0	1.0000	.9964	.9929	.9893	.9858	.9822	.9787	.9752	.9717	.9682	.9648	.9613
0.5	.9579	.9544	.9510	.9476	.9442	.9408	.9375	.9341	.9308	.9274	.9241	.9208
1.0	.9175	.9142	.9109	.9077	.9044	.9012	.8980	.8947	.8915	.8883	.8852	.8820
1.5	.8788	.8757	.8726	.8694	.8663	.8632	.8601	.8570	.8540	.8509	.8479	.8448
2.0	.8418	.8388	.8358	.8328	.8298	.8268	.8239	.8209	.8180	.8151	.8121	.8092
2.5	.8063	.8034	.8006	.7977	.7948	.7920	.7892	.7863	.7835	.7807	.7779	.7751
3.0	.7724	.7696	.7668	.7641	.7613	.7586	.7559	.7532	.7505	.7478	.7451	.7425
3.5	.7398	.7372	.7345	.7319	.7293	.7267	.7241	.7215	.7189	.7163	.7137	.7112
4.0	.7086	.7061	.7036	.7010	.6985	.6960	.6935	.6911	.6886	.6861	.6837	.6812
4.5	.6788	.6763	.6739	.6715	.6691	.6667	.6643	.6619	.6596	.6572	.6548	.6525
5.0	.6502	.6478	.6455	.6432	.6409	.6386	.6363	.6340	.6318	.6295	.6273	.6250
5.5	.6228	.6205	.6183	.6161	.6139	.6117	.6095	.6073	.6051	.6030	.6008	.5987
6.0	.5965	.5944	.5923	.5901	.5880	.5859	.5838	.5817	.5796	.5776	.5755	.5734
6.5	.5714	.5693	.5673	.5653	.5632	.5612	.5592	.5572	.5552	.5532	.5513	.5493
7.0	.5473	.5454	.5434	.5415	.5395	.5376	.5357	.5337	.5318	.5299	.5280	.5261
7.5	.5242	.5224	.5205	.5186	.5168	.5149	.5131	.5112	.5094	.5076	.5058	.5040
8.0	.5022	.5004	.4986	.4968	.4950	.4932	.4915	.4897	.4879	.4862	.4845	.4827
8.5	.4810	.4793	.4776	.4758	.4741	.4724	.4708	.4691	.4674	.4657	.4640	.4624
9.0	.4607	.4591	.4574	.4558	.4542	.4525	.4509	.4493	.4477	.4461	.4445	.4429
9.5	.4413	.4397	.4382	.4366	.4350	.4335	.4319	.4304	.4288	.4273	.4258	.4242
10.0	.4227	.4212	.4197	.4182	.4167	.4152	.4137	.4122	.4108	.4093	.4078	.4064
10.5	.4049	.4035	.4020	.4006	.3991	.3977	.3963	.3949	.3934	.3920	.3906	.3892
11.0	.3878	.3865	.3851	.3837	.3823	.3809	.3796	.3782	.3769	.3755	.3742	.3728
11.5	.3715	.3702	.3688	.3675	.3662	.3649	.3636	.3623	.3610	.3597	.3584	.3571
12.0	.3558	.3546	.3533	.3520	.3508	.3495	.3483	.3470	.3458	.3445	.3433	.3421
12.5	.3408	.3396	.3384	.3372	.3360	.3348	.3336	.3324	.3312	.3300	.3288	.3277
13.0	.3265	.3253	.3242	.3230	.3218	.3207	.3195	.3184	.3172	.3161	.3150	.3139
13.5	.3127	.3116	.3105	.3094	.3083	.3072	.3061	.3050	.3039	.3028	.3017	.3006
14.0	.2996	.2985	.2974	.2963	.2953	.2942	.2932	.2921	.2911	.2900	.2890	.2880
14.5	.2869	.2859	.2849	.2839	.2828	.2818	.2808	.2798	.2788	.2778	.2768	.2758

Iron – 55

2.60 Years

Months	Weeks											
	0	1	2	3	4	5	6	7	8	9	10	11
0	1.0000	.9949	.9898	.9847	.9797	.9747	.9697	.9647	.9598	.9549	.9500	.9452
3	.9403	.9355	.9307	.9260	.9212	.9165	.9118	.9072	.9025	.8979	.8933	.8888
6	.8842	.8797	.8752	.8707	.8663	.8618	.8574	.8531	.8487	.8444	.8400	.8357
9	.8315	.8272	.8230	.8188	.8146	.8104	.8063	.8022	.7981	.7940	.7899	.7859
1 Year	.7819	.7779	.7739	.7699	.7660	.7621	.7582	.7543	.7504	.7466	.7428	.7390
3	.7352	.7314	.7277	.7240	.7203	.7166	.7129	.7093	.7057	.7020	.6985	.6949
6	.6913	.6878	.6843	.6808	.6773	.6738	.6704	.6670	.6636	.6602	.6568	.6534
9	.6501	.6468	.6435	.6402	.6369	.6336	.6304	.6272	.6240	.6208	.6176	.6144
2 Years	.6113	.6082	.6051	.6020	.5989	.5958	.5928	.5897	.5867	.5837	.5807	.5778
3	.5748	.5719	.5690	.5660	.5632	.5603	.5574	.5546	.5517	.5489	.5461	.5433
6	.5405	.5378	.5350	.5323	.5296	.5268	.5241	.5215	.5188	.5161	.5135	.5109
9	.5083	.5057	.5031	.5005	.4980	.4954	.4929	.4904	.4878	.4854	.4829	.4804
3 Years	.4779	.4755	.4731	.4706	.4682	.4658	.4635	.4611	.4587	.4564	.4541	.4517
3	.4494	.4471	.4448	.4426	.4403	.4381	.4358	.4336	.4314	.4292	.4270	.4248
6	.4226	.4204	.4183	.4162	.4140	.4119	.4098	.4077	.4056	.4036	.4015	.3994
9	.3974	.3954	.3933	.3913	.3893	.3873	.3854	.3834	.3814	.3795	.3775	.3756
4 Years	.3737	.3718	.3699	.3680	.3661	.3642	.3624	.3605	.3587	.3568	.3550	.3532
3	.3514	.3496	.3478	.3460	.3443	.3425	.3407	.3390	.3373	.3355	.3338	.3321
6	.3304	.3287	.3270	.3254	.3237	.3221	.3204	.3188	.3171	.3155	.3139	.3123
9	.3107	.3091	.3075	.3060	.3044	.3028	.3013	.2998	.2982	.2967	.2952	.2937
5 Years	.2922	.2907	.2892	.2877	.2862	.2848	.2833	.2819	.2804	.2790	.2776	.2761
3	.2747	.2733	.2719	.2705	.2692	.2678	.2664	.2650	.2637	.2623	.2610	.2597
6	.2583	.2570	.2557	.2544	.2531	.2518	.2505	.2492	.2480	.2467	.2454	.2442
9	.2429	.2417	.2404	.2392	.2380	.2368	.2356	.2344	.2332	.2320	.2308	.2296
6 Years	.2284	.2273	.2261	.2249	.2238	.2226	.2215	.2204	.2193	.2181	.2170	.2159

Iron – 59

45.6 Days

Days	Hours											
	0	6	12	18	24	30	36	42	48	54	60	66
0	1.0000	.9962	.9924	.9887	.9849	.9812	.9775	.9737	.9701	.9664	.9627	.9591
3	.9554	.9518	.9482	.9446	.9410	.9374	.9339	.9303	.9268	.9233	.9198	.9163
6	.9128	.9094	.9059	.9025	.8891	.8957	.8923	.8889	.8855	.8821	.8788	.8755
9	.8721	.8688	.8655	.8623	.8590	.8557	.8525	.8492	.8460	.8428	.8396	.8364
12	.8333	.8301	.8270	.8238	.8207	.8176	.8145	.8114	.8083	.8052	.8022	.7991
15	.7961	.7931	.7901	.7871	.7841	.7811	.7782	.7752	.7723	.7693	.7664	.7635
18	.7606	.7577	.7549	.7520	.7492	.7463	.7435	.7407	.7379	.7351	.7323	.7295
21	.7267	.7240	.7212	.7185	.7158	.7130	.7103	.7076	.7050	.7023	.6996	.6970
24	.6943	.6917	.6891	.6865	.6839	.6813	.6787	.6761	.6735	.6710	.6684	.6659
27	.6634	.6609	.6584	.6559	.6534	.6509	.6484	.6460	.6435	.6411	.6386	.6362
1 Month	.6338	.6314	.6290	.6266	.6242	.6219	.6195	.6172	.6148	.6125	.6102	.6079
3	.6055	.6033	.6010	.5987	.5964	.5942	.5919	.5897	.5874	.5852	.5830	.5808
6	.5786	.5764	.5742	.5720	.5698	.5677	.5655	.5634	.5612	.5591	.5570	.5549
9	.5528	.5507	.5486	.5465	.5444	.5424	.5403	.5383	.5362	.5342	.5322	.5301
12	.5281	.5261	.5241	.5221	.5202	.5182	.5162	.5143	.5123	.5104	.5084	.5065
15	.5046	.5027	.5008	.4989	.4970	.4951	.4932	.4913	.4895	.4876	.4858	.4839
18	.4821	.4803	.4784	.4766	.4748	.4730	.4712	.4694	.4677	.4659	.4641	.4624
21	.4606	.4589	.4571	.4554	.4536	.4519	.4502	.4485	.4468	.4451	.4434	.4417
24	.4401	.4384	.4367	.4351	.4334	.4318	.4301	.4285	.4269	.4253	.4237	.4220
27	.4204	.4189	.4173	.4157	.4141	.4125	.4110	.4094	.4079	.4063	.4048	.4032
2 Months	.4017	.4002	.3987	.3972	.3956	.3941	.3926	.3912	.3897	.3882	.3867	.3853
3	.3838	.3823	.3809	.3794	.3780	.3766	.3751	.3737	.3723	.3709	.3695	.3681
6	.3667	.3653	.3639	.3625	.3612	.3598	.3584	.3571	.3557	.3544	.3530	.3517
9	.3503	.3490	.3477	.3464	.3451	.3437	.3424	.3411	.3399	.3386	.3373	.3360
12	.3347	.3335	.3322	.3309	.3297	.3284	.3272	.3259	.3247	.3235	.3222	.3210
15	.3198	.3186	.3174	.3162	.3150	.3138	.3126	.3114	.3102	.3091	.3079	.3067
18	.3055	.3044	.3032	.3021	.3009	.2998	.2987	.2975	.2964	.2953	.2942	.2930
21	.2919	.2908	.2897	.2886	.2875	.2864	.2853	.2843	.2832	.2821	.2810	.2800
24	.2789	.2779	.2768	.2758	.2747	.2737	.2726	.2716	.2706	.2695	.2685	.2675
27	.2665	.2655	.2645	.2635	.2625	.2615	.2605	.2595	.2585	.2575	.2565	.2556

Mercury – 197

65 Hours

Hours	Hours											
	0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5
0	1.0000	.9947	.9894	.9841	.9789	.9737	.9685	.9634	.9582	.9531	.9481	.9430
6	.9380	.9330	.9281	.9231	.9182	.9133	.9085	.9037	.8989	.8941	.8893	.8846
12	.8799	.8752	.8706	.8659	.8613	.8567	.8522	.8476	.8431	.8387	.8342	.8298
18	.8253	.8210	.8166	.8123	.8079	.8036	.7994	.7951	.7909	.7867	.7825	.7783
1 Day	.7742	.7701	.7660	.7619	.7579	.7538	.7498	.7458	.7419	.7379	.7340	.7301
6	.7262	.7223	.7185	.7147	.7109	.7071	.7033	.6996	.6959	.6922	.6885	.6848
12	.6812	.6776	.6740	.6704	.6668	.6633	.6598	.6562	.6528	.6493	.6458	.6424
18	.6390	.6356	.6322	.6288	.6255	.6222	.6189	.6156	.6123	.6090	.6058	.6026
2 Days	.5994	.5962	.5930	.5899	.5867	.5836	.5805	.5774	.5743	.5713	.5683	.5652
6	.5622	.5592	.5563	.5533	.5504	.5474	.5445	.5416	.5388	.5359	.5330	.5302
12	.5274	.5246	.5218	.5190	.5163	.5135	.5108	.5081	.5054	.5027	.5000	.4973
18	.4947	.4921	.4894	.4868	.4843	.4817	.4791	.4766	.4740	.4715	.4690	.4665
3 Days	.4640	.4616	.4591	.4567	.4542	.4518	.4494	.4470	.4447	.4423	.4399	.4376
6	.4353	.4330	.4307	.4284	.4261	.4238	.4216	.4193	.4171	.4149	.4127	.4105
12	.4083	.4061	.4040	.4018	.3997	.3976	.3954	.3933	.3912	.3892	.3871	.3850
18	.3830	.3810	.3789	.3769	.3749	.3729	.3709	.3690	.3670	.3650	.3631	.3612
4 Days	.3593	.3573	.3554	.3536	.3517	.3498	.3479	.3461	.3443	.3424	.3406	.3388
6	.3370	.3352	.3334	.3316	.3299	.3281	.3264	.3246	.3229	.3212	.3195	.3178
12	.3161	.3144	.3127	.3111	.3094	.3078	.3061	.3045	.3029	.3013	.2997	.2981
18	.2965	.2949	.2934	.2918	.2903	.2887	.2872	.2856	.2841	.2826	.2811	.2796
5 Days	.2781	.2767	.2752	.2737	.2723	.2708	.2694	.2679	.2665	.2651	.2637	.2623
6	.2609	.2595	.2581	.2568	.2554	.2540	.2527	.2513	.2500	.2487	.2473	.2460
12	.2447	.2434	.2421	.2408	.2396	.2383	.2370	.2358	.2345	.2333	.2320	.2308
18	.2296	.2283	.2271	.2259	.2247	.2235	.2223	.2211	.2200	.2188	.2176	.2165
6 Days	.2153	.2142	.2130	.2119	.2108	.2097	.2085	.2074	.2063	.2052	.2041	.2031
6	.2020	.2009	.1998	.1988	.1977	.1967	.1956	.1946	.1935	.1925	.1915	.1905
12	.1895	.1885	.1875	.1865	.1855	.1845	.1835	.1825	.1816	.1806	.1796	.1787
18	.1777	.1768	.1758	.1749	.1740	.1730	.1721	.1712	.1703	.1694	.1685	.1676
7 Days	.1667	.1658	.1649	.1641	.1632	.1623	.1615	.1606	.1597	.1589	.1581	.1572

Phosphorus – 32

14.28 Days

Days	Hours											
	0	2	4	6	8	10	12	14	16	18	20	22
0	1.0000	.9960	.9919	.9879	.9840	.9800	.9760	.9721	.9682	.9642	.9604	.9565
1	.9526	.9488	.9449	.9411	.9373	.9335	.9298	.9260	.9223	.9186	.9149	.9112
2	.9075	.9038	.9002	.8965	.8929	.8893	.8857	.8821	.8786	.8750	.8715	.8680
3	.8645	.8610	.8575	.8541	.8506	.8472	.8438	.8404	.8370	.8336	.8302	.8269
4	.8235	.8202	.8169	.8136	.8103	.8070	.8038	.8005	.7973	.7941	.7909	.7877
5	.7845	.7813	.7782	.7750	.7719	.7688	.7657	.7626	.7595	.7565	.7534	.7504
6	.7473	.7443	.7413	.7383	.7353	.7324	.7294	.7265	.7235	.7206	.7177	.7148
7	.7119	.7091	.7062	.7033	.7005	.6977	.6949	.6921	.6893	.6865	.6837	.6809
8	.6782	.6755	.6727	.6700	.6673	.6646	.6619	.6593	.6566	.6540	.6513	.6437
9	.6461	.6435	.6409	.6383	.6357	.6331	.6306	.6280	.6255	.6230	.6205	.6179
10	.6155	.6130	.6105	.6080	.6056	.6031	.6007	.5983	.5959	.5935	.5911	.5887
11	.5863	.5839	.5816	.5792	.5769	.5746	.5722	.5699	.5676	.5653	.5631	.5608
12	.5585	.5563	.5540	.5518	.5495	.5473	.5451	.5429	.5407	.5385	.5364	.5342
13	.5321	.5299	.5278	.5256	.5235	.5214	.5193	.5172	.5151	.5130	.5110	.5089
14	.5068	.5048	.5028	.5007	.4987	.4967	.4947	.4927	.4907	.4887	.4867	.4848
15	.4828	.4809	.4789	.4770	.4751	.4732	.4713	.4693	.4675	.4656	.4637	.4618
16	.4600	.4581	.4562	.4544	.4526	.4507	.4489	.4471	.4453	.4435	.4417	.4399
17	.4382	.4364	.4346	.4329	.4311	.4294	.4277	.4259	.4242	.4225	.4208	.4191
18	.4174	.4157	.4140	.4124	.4107	.4090	.4074	.4057	.4041	.4025	.4009	.3992
19	.3976	.3960	.3944	.3928	.3912	.3897	.3881	.3865	.3850	.3834	.3819	.3803
20	.3788	.3773	.3757	.3742	.3727	.3712	.3697	.3682	.3667	.3652	.3638	.3623
21	.3608	.3594	.3579	.3565	.3550	.3536	.3522	.3508	.3493	.3479	.3465	.3451
22	.3437	.3424	.3410	.3396	.3382	.3369	.3355	.3341	.3328	.3314	.3301	.3288
23	.3275	.3261	.3248	.3235	.3222	.3209	.3196	.3183	.3170	.3157	.3145	.3132
24	.3119	.3107	.3094	.3082	.3069	.3057	.3045	.3032	.3020	.3008	.2996	.2984
25	.2972	.2960	.2948	.2936	.2924	.2912	.2900	.2889	.2877	.2865	.2854	.2842
26	.2831	.2819	.2808	.2797	.2785	.2774	.2763	.2752	.2741	.2730	.2719	.2708
27	.2697	.2686	.2675	.2664	.2653	.2643	.2632	.2621	.2611	.2600	.2590	.2579
28	.2569	.2559	.2548	.2538	.2528	.2517	.2507	.2497	.2487	.2477	.2467	.2457
29	.2447	.2437	.2427	.2418	.2408	.2398	.2388	.2379	.2369	.2360	.2350	.2341

Phosphorus – 33

24.4 Days

Days	Hours											
	0	2	4	6	8	10	12	14	16	18	20	22
0	1.0000	.9976	.9953	.9929	.9906	.9882	.9859	.9836	.9812	.9789	.9766	.9743
1	.9720	.9697	.9674	.9651	.9628	.9606	.9583	.9560	.9538	.9515	.9493	.9470
2	.9448	.9425	.9403	.9381	.9359	.9337	.9314	.9292	.9270	.9249	.9227	.9205
3	.9183	.9161	.9140	.9118	.9097	.9075	.9054	.9032	.9011	.8989	.8968	.8947
4	.8926	.8905	.8884	.8863	.8842	.8821	.8800	.8779	.8758	.8738	.8717	.8696
5	.8676	.8655	.8635	.8614	.8594	.8574	.8554	.8533	.8513	.8493	.8473	.8453
6	.8433	.8413	.8393	.8373	.8353	.8334	.8314	.8294	.8275	.8255	.8236	.8216
7	.8197	.8177	.8158	.8139	.8119	.8100	.8081	.8062	.8043	.8024	.8005	.7986
8	.7967	.7948	.7929	.7911	.7892	.7873	.7855	.7836	.7818	.7799	.7781	.7762
9	.7744	.7726	.7707	.7689	.7671	.7653	.7635	.7617	.7599	.7581	.7563	.7545
10	.7527	.7509	.7492	.7474	.7456	.7439	.7421	.7403	.7386	.7368	.7351	.7334
11	.7316	.7299	.7282	.7264	.7247	.7230	.7213	.7196	.7179	.7162	.7145	.7128
12	.7111	.7095	.7078	.7061	.7044	.7028	.7011	.6994	.6978	.6961	.6945	.6929
13	.6912	.6896	.6880	.6863	.6847	.6831	.6815	.6799	.6783	.6766	.6750	.6735
14	.6719	.6703	.6687	.6671	.6655	.6640	.6624	.6608	.6593	.6577	.6561	.6546
15	.6530	.6515	.6500	.6484	.6469	.6454	.6438	.6423	.6408	.6393	.6378	.6363
16	.6348	.6332	.6318	.6303	.6288	.6273	.6258	.6243	.6228	.6214	.6199	.6184
17	.6170	.6155	.6141	.6126	.6112	.6097	.6083	.6068	.6054	.6040	.6025	.6011
18	.5997	.5983	.5969	.5954	.5940	.5926	.5912	.5898	.5884	.5871	.5857	.5843
19	.5829	.5815	.5801	.5788	.5774	.5760	.5747	.5733	.5720	.5706	.5693	.5679
20	.5666	.5652	.5639	.5626	.5612	.5599	.5586	.5573	.5559	.5546	.5533	.5520
21	.5507	.5494	.5481	.5468	.5455	.5442	.5429	.5417	.5404	.5391	.5378	.5365
22	.5353	.5340	.5327	.5315	.5302	.5290	.5277	.5265	.5252	.5240	.5228	.5215
23	.5203	.5191	.5178	.5166	.5154	.5142	.5129	.5117	.5105	.5093	.5081	.5069
24	.5057	.5045	.5033	.5021	.5009	.4998	.4986	.4974	.4962	.4951	.4939	.4927
25	.4915	.4904	.4892	.4881	.4869	.4858	.4846	.4835	.4823	.4812	.4801	.4789
26	.4778	.4767	.4755	.4744	.4733	.4722	.4710	.4699	.4688	.4677	.4666	.4655
27	.4644	.4633	.4622	.4611	.4600	.4589	.4579	.4568	.4557	.4546	.4535	.4525
28	.4514	.4503	.4493	.4482	.4471	.4461	.4450	.4440	.4429	.4419	.4408	.4398
29	.4388	.4377	.4367	.4356	.4346	.4336	.4326	.4315	.4305	.4295	.4285	.4275
30	.4265	.4255	.4244	.4234	.4224	.4214	.4204	.4195	.4185	.4175	.4165	.4155
31	.4145	.4135	.4126	.4116	.4106	.4096	.4087	.4077	.4067	.4058	.4048	.4039
32	.4029	.4020	.4010	.4001	.3991	.3982	.3972	.3963	.3953	.3944	.3935	.3926
33	.3916	.3907	.3898	.3889	.3879	.3870	.3861	.3852	.3843	.3834	.3825	.3816
34	.3807	.3798	.3789	.3780	.3771	.3762	.3753	.3744	.3735	.3726	.3717	.3709

Potassium – 42 12.36 Hours

Hours	Minutes											
	0	5	10	15	20	25	30	35	40	45	50	55
0	1.0000	.9953	.9907	.9861	.9815	.9769	.9723	.9678	.9633	.9588	.9543	.9499
1	.9455	.9411	.9367	.9323	.9280	.9236	.9193	.9150	.9108	.9065	.9023	.8981
2	.8939	.8897	.8856	.8815	.8773	.8733	.8692	.8651	.8611	.8571	.8531	.8491
3	.8452	.8412	.8373	.8334	.8295	.8256	.8218	.8180	.8141	.8103	.8066	.8028
4	.7991	.7953	.7916	.7879	.7843	.7806	.7770	.7733	.7697	.7661	.7626	.7590
5	.7555	.7520	.7485	.7450	.7415	.7380	.7346	.7312	.7278	.7244	.7210	.7176
6	.7143	.7110	.7076	.7043	.7011	.6978	.6945	.6913	.6881	.6849	.6817	.6785
7	.6753	.6722	.6690	.6659	.6628	.6597	.6567	.6536	.6505	.6475	.6445	.6415
8	.6385	.6355	.6326	.6296	.6267	.6238	.6208	.6179	.6151	.6122	.6093	.6065
9	.6037	.6009	.5981	.5953	.5925	.5897	.5870	.5842	.5815	.5788	.5761	.5734
10	.5708	.5681	.5654	.5628	.5602	.5576	.5550	.5524	.5498	.5472	.5447	.5422
11	.5396	.5371	.5346	.5321	.5296	.5272	.5247	.5223	.5198	.5174	.5150	.5126
12	.5102	.5078	.5055	.5031	.5007	.4984	.4961	.4938	.4915	.4892	.4869	.4846
13	.4824	.4801	.4779	.4757	.4734	.4712	.4690	.4668	.4647	.4625	.4603	.4582
14	.4561	.4539	.4518	.4497	.4476	.4455	.4435	.4414	.4393	.4373	.4352	.4332
15	.4312	.4292	.4272	.4252	.4232	.4212	.4193	.4173	.4154	.4134	.4115	.4096
16	.4077	.4058	.4039	.4020	.4001	.3983	.3964	.3946	.3927	.3909	.3891	.3873
17	.3854	.3836	.3819	.3801	.3783	.3765	.3748	.3730	.3713	.3696	.3678	.3661
18	.3644	.3627	.3610	.3594	.3577	.3560	.3543	.3527	.3511	.3494	.3478	.3462
19	.3445	.3429	.3413	.3398	.3382	.3366	.3350	.3335	.3319	.3304	.3288	.3273
20	.3258	.3242	.3227	.3212	.3197	.3182	.3168	.3153	.3138	.3123	.3109	.3094
21	.3080	.3066	.3051	.3037	.3023	.3009	.2995	.2981	.2967	.2953	.2939	.2926
22	.2912	.2898	.2885	.2871	.2858	.2845	.2831	.2818	.2805	.2792	.2779	.2766
23	.2753	.2740	.2728	.2715	.2702	.2690	.2677	.2665	.2652	.2640	.2627	.2615
24	.2603	.2591	.2579	.2567	.2555	.2543	.2531	.2519	.2507	.2496	.2484	.2473

Potassium – 43 22.4 Hours

Hours	Minutes											
	0	10	20	30	40	50	60	70	80	90	100	110
0	1.0000	.9949	.9897	.9846	.9796	.9745	.9695	.9645	.9596	.9546	.9497	.9448
2	.9400	.9352	.9303	.9256	.9208	.9161	.9113	.9067	.9020	.8974	.8927	.8881
4	.8836	.8790	.8745	.8700	.8655	.8611	.8567	.8522	.8479	.8435	.8392	.8348
6	.8306	.8263	.8220	.8178	.8136	.8094	.8052	.8011	.7970	.7929	.7888	.7847
8	.7807	.7767	.7727	.7687	.7648	.7608	.7569	.7530	.7492	.7453	.7415	.7377
10	.7339	.7301	.7263	.7226	.7189	.7152	.7115	.7078	.7042	.7006	.6970	.6934
12	.6898	.6863	.6827	.6792	.6757	.6723	.6688	.6654	.6619	.6585	.6551	.6518
14	.6484	.6451	.6418	.6385	.6352	.6319	.6287	.6254	.6222	.6190	.6158	.6127
16	.6095	.6064	.6033	.6001	.5971	.5940	.5909	.5879	.5849	.5819	.5789	.5759
18	.5729	.5700	.5670	.5641	.5612	.5583	.5555	.5526	.5498	.5469	.5441	.5413
20	.5385	.5358	.5330	.5303	.5276	.5248	.5221	.5195	.5168	.5141	.5115	.5088
22	.5062	.5036	.5010	.4985	.4959	.4933	.4908	.4883	.4858	.4833	.4808	.4783
1 Day	.4758	.4734	.4710	.4685	.4661	.4637	.4613	.4590	.4566	.4543	.4519	.4496
2	.4473	.4450	.4427	.4404	.4382	.4359	.4337	.4314	.4292	.4270	.4248	.4226
4	.4204	.4183	.4161	.4140	.4119	.4097	.4076	.4055	.4035	.4014	.3993	.3973
6	.3952	.3932	.3912	.3891	.3871	.3852	.3832	.3812	.3792	.3773	.3754	.3734
8	.3715	.3696	.3677	.3658	.3639	.3620	.3602	.3583	.3565	.3546	.3528	.3510
10	.3492	.3474	.3456	.3438	.3421	.3403	.3386	.3368	.3351	.3334	.3317	.3299
12	.3282	.3266	.3249	.3232	.3215	.3199	.3182	.3166	.3150	.3134	.3117	.3101
14	.3085	.3070	.3054	.3038	.3022	.3007	.2991	.2976	.2961	.2946	.2930	.2915
16	.2900	.2885	.2871	.2856	.2841	.2826	.2812	.2797	.2783	.2769	.2755	.2740
18	.2726	.2712	.2698	.2684	.2671	.2657	.2643	.2630	.2616	.2603	.2589	.2576
20	.2563	.2549	.2536	.2523	.2510	.2497	.2485	.2472	.2459	.2446	.2434	.2421
22	.2409	.2396	.2384	.2372	.2360	.2348	.2335	.2323	.2312	.2300	.2288	.2276
2 Days	.2264	.2253	.2241	.2230	.2218	.2207	.2195	.2184	.2173	.2162	.2150	.2139

Selenium – 75

120.4 Days

Days	Days									
	0	1	2	3	4	5	6	7	8	9
0	1.0000	.9943	.9886	.9829	.9772	.9716	.9660	.9605	.9550	.9495
10	.9441	.9386	.9332	.9279	.9226	.9173	.9120	.9068	.9016	.8964
20	.8912	.8861	.8810	.8760	.8710	.8660	.8610	.8560	.8511	.8462
1 Month	.8414	.8366	.8317	.8270	.8222	.8175	.8128	.8081	.8035	.7989
10	.7943	.7898	.7852	.7807	.7762	.7718	.7673	.7629	.7586	.7542
20	.7499	.7456	.7413	.7370	.7328	.7286	.7244	.7203	.7161	.7120
2 Months	.7079	.7039	.6998	.6958	.6918	.6878	.6839	.6800	.6761	.6722
10	.6683	.6645	.6607	.6569	.6531	.6494	.6456	.6419	.6382	.6346
20	.6309	.6273	.6237	.6201	.6166	.6130	.6095	.6060	.6025	.5991
3 Months	.5956	.5922	.5888	.5854	.5821	.5787	.5754	.5721	.5688	.5656
10	.5623	.5591	.5559	.5527	.5495	.5464	.5432	.5401	.5370	.5339
20	.5309	.5278	.5248	.5218	.5188	.5158	.5128	.5099	.5070	.5040
4 Months	.5012	.4983	.4954	.4926	.4897	.4869	.4841	.4814	.4786	.4758
10	.4731	.4704	.4677	.4650	.4623	.4597	.4571	.4544	.4518	.4492
20	.4466	.4441	.4415	.4390	.4365	.4340	.4315	.4290	.4265	.4241
5 Months	.4217	.4192	.4168	.4144	.4121	.4097	.4073	.4050	.4027	.4004
10	.3981	.3958	.3935	.3913	.3890	.3868	.3846	.3823	.3802	.3780
20	.3758	.3736	.3715	.3694	.3672	.3651	.3630	.3610	.3589	.3568
6 Months	.3548	.3527	.3507	.3487	.3467	.3447	.3427	.3408	.3388	.3369
10	.3349	.3330	.3311	.3292	.3273	.3254	.3236	.3217	.3199	.3180
20	.3162	.3144	.3126	.3108	.3090	.3072	.3055	.3037	.3020	.3002
7 Months	.2985	.2968	.2951	.2934	.2917	.2900	.2884	.2867	.2851	.2834
10	.2818	.2802	.2786	.2770	.2754	.2738	.2722	.2707	.2691	.2676
20	.2660	.2645	.2630	.2615	.2600	.2585	.2570	.2555	.2541	.2526
8 Months	.2512	.2497	.2483	.2469	.2454	.2440	.2426	.2412	.2398	.2385

Sodium – 24

14.96 Hours

Hours	Minutes											
	0	10	20	30	40	50	60	70	80	90	100	110
0	1.0000	.9923	.9847	.9771	.9696	.9621	.9547	.9474	.9401	.9329	.9257	.9186
2	.9115	.9045	.8975	.8906	.8838	.8770	.8702	.8635	.8569	.8503	.8438	.8373
4	.8308	.8244	.8181	.8118	.8056	.7994	.7932	.7871	.7811	.7750	.7691	.7632
6	.7573	.7515	.7457	.7400	.7343	.7286	.7230	.7174	.7119	.7065	.7010	.6956
8	.6903	.6850	.6797	.6745	.6693	.6641	.6590	.6540	.6489	.6439	.6390	.6341
10	.6292	.6243	.6195	.6148	.6100	.6054	.6007	.5961	.5915	.5869	.5824	.5779
12	.5735	.5691	.5647	.5604	.5561	.5518	.5475	.5433	.5391	.5350	.5309	.5268
14	.5227	.5187	.5147	.5108	.5068	.5029	.4991	.4952	.4914	.4876	.4839	.4802
16	.4765	.4728	.4692	.4656	.4620	.4584	.4549	.4514	.4479	.4445	.4411	.4377
18	.4343	.4310	.4277	.4244	.4211	.4179	.4146	.4115	.4083	.4051	.4020	.3989
20	.3959	.3928	.3898	.3868	.3838	.3809	.3779	.3750	.3722	.3693	.3665	.3636
22	.3608	.3581	.3553	.3526	.3499	.3472	.3445	.3418	.3392	.3366	.3340	.3314
1 Day	.3289	.3264	.3239	.3214	.3189	.3164	.3140	.3116	.3092	.3068	.3045	.3021
2	.2998	.2975	.2952	.2929	.2907	.2884	.2862	.2840	.2818	.2797	.2775	.2754
4	.2733	.2712	.2691	.2670	.2649	.2629	.2609	.2589	.2569	.2549	.2530	.2510
6	.2491	.2472	.2453	.2434	.2415	.2396	.2378	.2360	.2342	.2324	.2306	.2288
8	.2270	.2253	.2236	.2218	.2201	.2184	.2168	.2151	.2134	.2118	.2102	.2085
10	.2069	.2053	.2038	.2022	.2006	.1991	.1976	.1960	.1945	.1930	.1916	.1901
12	.1886	.1872	.1857	.1843	.1829	.1815	.1801	.1787	.1773	.1760	.1746	.1733
14	.1719	.1706	.1693	.1680	.1667	.1654	.1641	.1629	.1616	.1604	.1592	.1579
16	.1567	.1555	.1543	.1531	.1519	.1508	.1496	.1485	.1473	.1462	.1451	.1440
18	.1428	.1417	.1407	.1396	.1385	.1374	.1364	.1353	.1343	.1333	.1322	.1312
20	.1302	.1292	.1282	.1272	.1262	.1253	.1243	.1234	.1224	.1215	.1205	.1196
22	.1187	.1178	.1169	.1160	.1151	.1142	.1133	.1124	.1116	.1107	.1099	.1090
2 Days	.1082	.1073	.1065	.1057	.1049	.1041	.1033	.1025	.1017	.1009	.1001	.0994

Strontium – 85

64 Days

Days	Days									
	0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5
0	1.0000	.9946	.9892	.9839	.9786	.9733	.9680	.9628	.9576	.9524
5	.9473	.9422	.9371	.9320	.9270	.9220	.9170	.9121	.9071	.9022
10	.8974	.8925	.8877	.8829	.8781	.8734	.8687	.8640	.8593	.8547
15	.8501	.8455	.8409	.8364	.8318	.8273	.8229	.8184	.8140	.8096
20	.8052	.8009	.7966	.7923	.7880	.7837	.7795	.7753	.7711	.7669
25	.7628	.7587	.7546	.7505	.7465	.7424	.7384	.7344	.7305	.7265
1 Month	.7226	.7187	.7148	.7109	.7071	.7033	.6995	.6957	.6920	.6882
5	.6845	.6808	.6771	.6735	.6698	.6662	.6626	.6590	.6555	.6519
10	.6484	.6449	.6414	.6380	.6345	.6311	.6277	.6243	.6209	.6176
15	.6142	.6109	.6076	.6043	.6011	.5978	.5946	.5914	.5882	.5850
20	.5819	.5787	.5756	.5725	.5694	.5663	.5633	.5602	.5572	.5542
25	.5512	.5482	.5453	.5423	.5394	.5365	.5336	.5307	.5278	.5250
2 Months	.5221	.5193	.5165	.5137	.5109	.5082	.5054	.5027	.5000	.4973
5	.4946	.4919	.4893	.4866	.4840	.4814	.4788	.4762	.4736	.4711
10	.4685	.4660	.4635	.4610	.4585	.4560	.4536	.4511	.4487	.4463
15	.4438	.4414	.4391	.4367	.4343	.4320	.4297	.4273	.4250	.4227
20	.4204	.4182	.4159	.4137	.4114	.4092	.4070	.4048	.4026	.4004
25	.3983	.3961	.3940	.3919	.3898	.3876	.3856	.3835	.3814	.3793
3 Months	.3773	.3753	.3732	.3712	.3692	3672	.3652	.3633	.3613	.3593
5	.3574	.3555	.3536	.3516	.3497	.3479	.3460	.3441	.3423	.3404
10	.3386	.3367	.3349	.3331	.3313	.3295	.3277	.3260	.3242	.3225
15	.3207	.3190	.3173	.3155	.3138	.3122	.3105	.3088	.3071	.3055
20	.3038	.3022	.3005	.2989	.2973	.2957	.2941	.2925	.2909	.2894
25	.2878	.2862	.2847	.2832	.2816	.2801	.2786	.2771	.2756	.2741
4 Months	.2726	.2712	.2697	.2682	.2668	.2653	.2639	.2625	.2611	.2597

Strontium – 87m

2.83 Hours

Minutes	Minutes									
	0	1	2	3	4	5	6	7	8	9
0	1.0000	.9959	.9919	.9878	.9838	.9798	.9758	.9718	.9679	.9639
10	.9600	.9561	.9522	.9483	.9445	.9406	.9368	.9330	.9292	.9254
20	.9216	.9178	.9141	.9104	.9067	.9030	.8993	.8956	.8920	.8884
30	.8847	.8811	.8775	.8740	.8704	.8669	.8633	.8598	.8563	.8528
40	.8493	.8459	.8424	.8390	.8356	.8322	.8288	.8254	.8221	.8187
50	.8154	.8121	.8087	.8055	.8022	.7989	.7956	.7924	.7892	.7860
1 Hour	.7828	.7796	.7764	.7732	.7701	.7669	.7638	.7607	.7576	.7545
10	.7515	.7484	.7453	.7423	.7393	.7363	.7333	.7303	.7273	.7243
20	.7214	.7185	.7155	.7126	.7097	.7068	.7039	.7011	.6982	.6954
30	.6925	.6897	.6869	.6841	.6813	.6785	.6758	.6730	.6703	.6676
40	.6648	.6621	.6594	.6567	.6541	.6514	.6488	.6461	.6435	.6409
50	.6382	.6356	.6331	.6305	.6279	.6253	.6228	.6203	.6177	.6152
2 Hours	.6127	.6102	.6077	.6053	.6028	.6003	.5979	.5955	.5930	.5906
10	.5882	.5858	.5834	.5810	.5787	.5763	.5740	.5716	.5693	.5670
20	.5647	.5624	.5601	.5578	.5555	.5533	.5510	.5488	.5465	.5443
30	.5421	.5399	.5377	.5355	.5333	.5311	.5290	.5268	.5247	.5225
40	.5204	.5183	.5162	.5141	.5120	.5099	.5078	.5057	.5037	.5016
50	.4996	.4976	.4955	.4935	.4915	.4895	.4875	.4855	.4835	.4816
3 Hours	.4796	.4777	.4757	.4738	.4718	.4699	.4680	.4661	.4642	.4623
10	.4604	.4585	.4567	.4548	.4530	.4511	.4493	.4475	.4456	.4438
20	.4420	.4402	.4384	.4366	.4348	.4331	.4313	.4296	.4278	.4261
30	.4243	.4226	.4209	.4192	.4175	.4158	.4141	.4124	.4107	.4090
40	.4074	.4057	.4040	.4024	.4008	.3991	.3975	.3959	.3943	.3927
50	.3911	.3895	.3879	.3863	.3847	.3832	.3816	.3800	.3785	.3770
4 Hours	.3754	.3739	.3724	.3708	.3693	.3678	.3663	.3648	.3634	.3619

Sulfur – 35

87.9 Days

Days	Days 0.	.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5
0	1.0000	.9961	.9921	.9882	.9844	.9805	.9766	.9728	.9689	.9651
5	.9613	.9576	.9538	.9500	.9463	.9426	.9389	.9352	.9315	.9278
10	.9242	.9205	.9169	.9133	.9097	.9061	.9026	.8990	.8955	.8920
15	.8884	.8849	.8815	.8780	.8745	.8711	.8677	.8643	.8609	.8575
20	.8541	.8507	.8474	.8441	.8407	.8374	.8341	.8308	.8276	.8243
25	.8211	.8178	.8146	.8114	.8082	.8050	.8019	.7987	.7956	.7924
1 Month	.7893	.7862	.7831	.7800	.7770	.7739	.7709	.7678	.7648	.7618
5	.7588	.7558	.7529	.7499	.7469	.7440	.7411	.7382	.7353	.7324
10	.7295	.7266	.7237	.7209	.7181	.7152	.7124	.7096	.7068	.7040
15	.7013	.6985	.6958	.6930	.6903	.6876	.6849	.6822	.6795	.6768
20	.6742	.6715	.6689	.6662	.6636	.6610	.6584	.6558	.6532	.6507
25	.6481	.6455	.6430	.6405	.6380	.6354	.6329	.6305	.6280	.6255
2 Months	.6230	.6206	.6182	.6157	.6133	.6109	.6085	.6061	.6037	.6013
5	.5990	.5956	.5943	.5919	.5896	.5873	.5850	.5827	.5804	.5781
10	.5758	.5735	.5713	.5690	.5668	.5646	.5623	.5601	.5579	.5557
15	.5535	.5514	.5492	.5470	.5449	.5427	.5406	.5385	.5364	.5342
20	.5321	.5300	.5280	.5259	.5238	.5218	.5197	.5177	.5156	.5136
25	.5116	.5096	.5075	.5056	.5036	.5016	.4996	.4976	.4957	.4937
3 Months	.4918	.4899	.4879	.4860	.4841	.4822	.4803	.4784	.4765	.4746
5	.4728	.4709	.4691	.4672	.4654	.4635	.4617	.4599	.4581	.4563
10	.4545	.4527	.4509	.4492	.4474	.4456	.4439	.4421	.4404	.4387
15	.4369	.4352	.4335	.4318	.4301	.4284	.4267	.4250	.4234	.4217
20	.4200	.4184	.4167	.4151	.4135	.4118	.4102	.4086	.4070	.4054
25	.4038	.4022	.4006	.3990	.3975	.3959	.3944	.3928	.3913	.3897
4 Months	.3882	.3867	.3851	.3836	.3821	.3806	.3791	.3776	.3761	.3747

Technetium – 99m

6.049 Hours

Minutes	Minutes 0	2	4	6	8	10	12	14	16	18
0	1.0000	.9962	.9924	.9885	.9848	.9810	.9772	.9735	.9697	.9660
20	.9623	.9586	.9550	.9513	.9477	.9440	.9404	.9368	.9332	.9296
40	.9261	.9225	.9190	.9155	.9120	.9085	.9050	.9015	.8981	.8946
1 Hour	.8912	.8878	.8844	.8810	.8776	.8743	.8709	.3676	.8642	.8609
20	.8576	.8543	.8511	.8478	.8446	.8413	.8381	.8349	.8317	.8285
40	.8253	.8222	.8190	.8159	.8127	.8096	.8065	.8034	.8004	.7973
2 Hours	.7942	.7912	.7882	.7851	.7821	.7791	.7761	.7732	.7702	.7673
20	.7643	.7614	.7585	.7556	.7527	.7498	.7469	.7440	.7412	.7384
40	.7355	.7327	.7299	.7271	.7243	.7215	.7188	.7160	.7133	.7105
3 Hours	.7078	.7051	.7024	.6997	.6970	.6944	.6917	.6890	.6864	.6838
20	.6812	.6785	.6759	.6734	.6708	.6682	.6656	.6631	.6606	.6580
40	.6555	.6530	.6505	.6480	.6455	.6430	.6406	.6381	.6357	.6332
4 Hours	.6308	.6284	.6260	.6236	.6212	.6188	.6164	.6141	.6117	.6094
20	.6070	.6047	.6024	.6001	.5978	.5955	.5932	.5909	.5887	.5864
40	.5842	.5819	.5797	.5775	.5753	.5731	.5709	.5687	.5665	.5643
5 Hours	.5622	.5600	.5579	.5557	.5536	.5515	.5494	.5473	.5452	.5431
20	.5410	.5389	.5369	.5348	.5328	.5307	.5287	.5267	.5246	.5226
40	.5206	.5186	.5166	.5147	.5127	.5107	.5088	.5068	.5049	.5029
6 Hours	.5010	.4991	.4972	.4953	.4934	.4915	.4896	.4877	.4859	.4840
20	.4821	.4803	.4784	.4766	.4748	.4730	.4712	.4694	.4676	.4658
40	.4640	.4622	.4604	.4587	.4569	.4552	.4534	.4517	.4499	.4482
7 Hours	.4465	.4448	.4431	.4414	.4397	.4380	.4363	.4347	.4330	.4313
20	.4297	.4280	.4264	.4248	.4231	.4215	.4199	.4183	.4167	.4151
40	.4135	.4119	.4103	.4088	.4072	.4056	.4041	.4025	.4010	.3994
8 Hours	.3979	.3964	.3949	.3934	.3919	.3904	.3889	.3874	.3859	.3844

Xenon – 133

5.27 Days

Days	Hours											
	0	1	2	3	4	5	6	7	8	9	10	11
0.0	1.0000	.9945	.9891	.9837	.9783	.9730	.9677	.9624	.9571	.9519	.9467	.9415
0.5	.9364	.9312	.9261	.9211	.9160	.9110	.9061	.9011	.8962	.8913	.8864	.8816
1.0	.8768	.8720	.8672	.8625	.8577	.8531	.8484	.8438	.8391	.8346	.8300	.8255
1.5	.8210	.8165	.8120	.8076	.8032	.7988	.7944	.7901	.7857	.7814	.7772	.7729
2.0	.7687	.7645	.7603	.7562	.7520	.7479	.7438	.7398	.7357	.7317	.7277	.7237
2.5	.7198	.7158	.7119	.7080	.7042	.7003	.6965	.6927	.6889	.6851	.6814	.6777
3.0	.6740	.6703	.6666	.6630	.6593	.6557	.6522	.6486	.6451	.6415	.6380	.6345
3.5	.6311	.6276	.6242	.6208	.6174	.6140	.6107	.6073	.6040	.6007	.5974	.5941
4.0	.5909	.5877	.5845	.5813	.5781	.5749	.5718	.5687	.5656	.5625	.5594	.5563
4.5	.5533	.5503	.5473	.5443	.5413	.5383	.5354	.5325	.5296	.5267	.5238	.5209
5.0	.5181	.5152	.5124	.5096	.5068	.5041	.5013	.4986	.4959	.4931	.4904	.4878
5.5	.4851	.4824	.4798	.4772	.4746	.4720	.4694	.4668	.4643	.4618	.4592	.4567
6.0	.4542	.4517	.4493	.4468	.4444	.4419	.4395	.4371	.4347	.4324	.4300	.4277
6.5	.4253	.4230	.4207	.4184	.4161	.4138	.4116	.4093	.4071	.4048	.4026	.4004
7.0	.3982	.3961	.3939	.3918	.3896	.3875	.3854	.3833	.3812	.3791	.3770	.3749
7.5	.3729	.3709	.3688	.3668	.3648	.3628	.3608	.3589	.3569	.3550	.3530	.3511
8.0	.3492	.3473	.3454	.3435	.3416	.3397	.3379	.3360	.3342	.3324	.3305	.3287
8.5	.3269	.3252	.3234	.3216	.3199	.3181	.3164	.3146	.3129	.3112	.3095	.3078
9.0	.3061	.3045	.3028	.3011	.2995	.2979	.2962	.2946	.2930	.2914	.2898	.2882
9.5	.2866	.2851	.2835	.2820	.2804	.2789	.2774	.2759	.2744	.2729	.2714	.2699
10.0	.2684	.2669	.2655	.2640	.2626	.2611	.2597	.2583	.2569	.2555	.2541	.2527
10.5	.2513	.2499	.2486	.2472	.2459	.2445	.2432	.2419	.2405	.2392	.2379	.2366
11.0	.2353	.2340	.2328	.2315	.2302	.2290	.2277	.2265	.2252	.2240	.2228	.2216
11.5	.2203	.2191	.2179	.2168	.2156	.2144	.2132	.2121	.2109	.2097	.2086	.2075
12.0	.2063	.2052	.2041	.2030	.2018	.2007	.1996	.1986	.1975	.1964	.1953	.1943

Zinc – 65

245 Days

Days	Days									
	0	2	4	6	8	10	12	14	16	18
0	1.0000	.9944	.9887	.9832	.9776	.9721	.9666	.9612	.9557	.9503
20	.9450	.9397	.9344	.9291	.9238	.9186	.9134	.9083	.9032	.8981
40	.8930	.8880	.8830	.8780	.8730	.8681	.8632	.8583	.8535	.8487
60	.8439	.8391	.8344	.8297	.8250	.8203	.8157	.8111	.8065	.8020
80	.7975	.7930	.7885	.7840	.7796	.7752	.7708	.7665	.7622	.7579
100	.7536	.7493	.7451	.7409	.7367	.7326	.7284	.7243	.7202	.7162
120	.7121	.7081	.7041	.7001	.6962	.6923	.6884	.6845	.6806	.6768
140	.6730	.6692	.6654	.6616	.6579	.6542	.6505	.6468	.6432	.6395
160	.6359	.6323	.6288	.6252	.6217	.6182	.6147	.6112	.6078	.6044
180	.6009	.5976	.5942	.5908	.5875	.5842	.5809	.5776	.5743	.5711
200	.5679	.5647	.5615	.5583	.5552	.5520	.5489	.5458	.5428	.5397
220	.5366	.5336	.5306	.5276	.5246	.5217	.5187	.5158	.5129	.5100
240	.5071	.5043	.5014	.4986	.4958	.4930	.4902	.4874	.4847	.4819
260	.4792	.4765	.4738	.4712	.4685	.4659	.4632	.4606	.4580	.4554
280	.4529	.4503	.4478	.4452	.4427	.4402	.4377	.4353	.4328	.4304
300	.4279	.4255	.4231	.4207	.4184	.4160	.4137	.4113	.4090	.4067
320	.4044	.4021	.3999	.3976	.3954	.3931	.3909	.3887	.3865	.3843
340	.3822	.3800	.3779	.3757	.3736	.3715	.3694	.3673	.3652	.3632
360	.3611	.3591	.3571	.3551	.3531	.3511	.3491	.3471	.3452	.3432
380	.3413	.3393	.3374	.3355	.3336	.3317	.3299	.3280	.3262	.3243
400	.3225	.3207	.3189	.3171	.3153	.3135	.3117	.3100	.3082	.3065
420	.3048	.3030	.3013	.2996	.2979	.2963	.2946	.2929	.2913	.2896
440	.2880	.2864	.2847	.2831	.2815	.2800	.2784	.2768	.2752	.2737
460	.2721	.2706	.2691	.2676	.2661	.2646	.2631	.2616	.2601	.2586
480	.2572	.2557	.2543	.2528	.2514	.2500	.2486	.2472	.2458	.2444

Office of Telecommunications Policy,
Executive Office of the President,
Washington, D.C., June 10, 1977.

Hon. Adlai E. Stevenson,
Hon. Wendell H. Ford,
Committee on Commerce, Science, and Transportation,
U.S. Senate, Washington, D.C.

Dear Senators: We are pleased to supply the following information in response to your letter of May 19, 1977, in connection with the Senate Committee on Commerce, Science, and Transportation hearings to review and evaluate federal radiation research and regulatory programs.

The activities of this office, relevant to your inquiry, are in the area of nonionizing radiation. They stem from our statutory responsibilities for the use of the radio-frequency spectrum by the Federal Government for telecommunications as set forth in Executive Order 11556 of September 4, 1970. OTP is also responsible for advising the President on national policy in the telecommunications field and for coordination of telecommunications activities and associated research. An integral part of these responsibilities is to ensure that the use of nonionizing electromagnetic energy does not harm either man or his environment or cause interference with other electronic equipment. It is important also to ensure that the many vital and beneficial services derived from the use of the spectrum are not unnecessarily curtailed or impaired.

In 1968, OTP initiated efforts to provide a focal point and review in this area and established the Electromagnetic Radiation Management Advisory Council (ERMAC) consisting of individuals with expertise in the various pertinent technical disciplines, to advise us on possible unintended or undesirable "side effects" which might be associated with the use of electromagnetic radiation. As a result of the ERMAC's activities, OTP recommended a coordinated Federal program to assess the biological effects of nonionizing radiation (0 Hz–300 GHz). This multiagency program is comprised of the independently funded activities of those agencies concerned with the use of electromagnetic radiation and/or health and the environment (e.g. the Department of Health, Education, and Welfare, the Environment Protection Agency, and the Department of Defense). Each agency is responsible for determining and controlling the specifics of its research efforts, taking into consideration program needs and recommended funding levels. OTP overviews, coordinates and provides a focal point and a forum for program efforts. An interdepartmental working group assists in providing intragovernmental coordination and the exchange of information. The ERMAC provides advice, recommendations, and review of program activities.

With regard to your request for fiscal information (see enclosure 1), it is important to note that this Office, in its coordinating and overview role, does not fund research or provide funds to participating agencies. Expenditures shown are for efforts which support the coordination process or provide information to the research community.

The responses to the specific questions posed in your letter are contained in enclosure 2.

We appreciate the opportunity to contribute to your review of Federal radiation research and regulatory programs and would be pleased to provide any additional information or assistance required.

Sincerely,

William J. Thaler.

Enclosures.

ENCLOSURE 1

OFFICE OF TELECOMMUNICATIONS POLICY

NON-IONIZING RADIATION* (Microwave and other radio-frequency 0 Hz - 300 GHz) *(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develomt	State/ Federal Liaison	Licensing; Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmnt	Other biological or physical effects	Other Studies (Explain) (1)
1968 In-House (Positions)												MY - 0.3 (2) EM - 25K (3) T - 34K (4)
1969 Extra-Mura (Funds) Total Fund												MY - 0.5 EM - 0 T - 20K
1970												MY - 0.7 EM - 0 T - 26K
1971												MY - 1 EM - 0 T - 35K
1972												MY - 1.2 EM - 0 T - 41K
1973												MY - 2.2 EM - 0 T - 41K
1974												MY - 2.2 EM - 0 T - 41K
1975												MY - 2.2 EM - 125.4K T - 166.4K
1976												MY - 2.2 EM - 54.1K T - 100.1K
1977												MY - 2.7 EM - 100K T - 146K est)
Est. 1978												MY - 3.2 EM - 120K T - 166K est)

applies to all years

Footnote Explanations

1. All activities are associated with OTP's program coordination and overview role.

2. Estimated total manpower in manyears (MY). This is a composite figure including staff, full and part time, administration/supervision and secretarial support. Since 1973 it has included one full time military detail and, in 1977, one MY support from DOC/OT was added.

3. Contracts to provide coordination and technical support including a computerized information system on biological effects of non-ionizing EMR (in $K).

4. Includes personnel cost based on an estimated averaged MY @ $30K (see note 2), contracts, and approximate costs for ERMAC - consists of travel to attend meetings only.

ENCLOSURE 2

The following are responses to the specific questions posed in your letter (numbers refer to your question number):

1. Reorganization Plan No. 1 of April 29, 1970, established OTP to replace the former Office of Telecommunications Management and, as amplified by Executive Order 11556 of September 1970, broadened the responsibility for, and gave increased impetus to, the office's activities in the nonionizing electromagnetic radiation area. OTP is specifically charged to:

"(b) Develop and set forth plans * * * programs with respect to telecommunications that will promote public interest * * *

"(e) Coordinate the telecommunications activities of the executive branch and formulate policies and standards, therefor, including * * * spectrum use * * *

"(g) Review telecommunications research * * * by Federal agencies. Identify competing, overlapping, duplicative or inefficient programs, and make recommendations to appropriate agency officials and to the Director of the Office of Management and Budget * * *"

Because OTP's activities involve coordinating all relevant Federal activities, it is necessary to incorporate active or interested participants as missions change or agencies are created with applicable missions and responsibilities in this area. For example, the creation of the Environmental Protection Agency (EPA) established a new agency concerned with the electromagnetic environment. The creation of the Occupational Safety and Health Administration (OSHA) in the Department of Labor, with the National Institute of Occupational Safety and Health (NIOSH) for research support, created new agencies with responsibilities for safety and the possible affects of electromagnetic energy on the worker. PL 90–602 gave specific regulatory responsibilities to BRH, affecting HEW's role in this area. The National Environmental Protection Act (NEPA) of 1969 focused additional attention on the potential environmental effects of nonionizing radiation. Additionally, new programs such as the interest of the National Cancer Institute (NCI) in the possible use of radio-frequencies/microwaves in the diagnosis and therapy of cancer, the NASA and ERDA activities associated with a possible solar power satellite system involving the transmission of energy by microwaves, and other energy related uses of the radio spectrum are being taken into account in the review and coordination process.

2. The OTP does not normally deal with state agencies; however, a number of the Federal agencies involved in the cooperative program do. We do maintain awareness of state activities pertaining to nonionizing radiation and provide information or assistance to state agencies as requested.

3. In discussing regulatory programs there are three principal areas of regulatory activity to consider:

Electronic product radiation: the control of emission of radiation from electronic products for the protection of public health and safety.

Occupational safety: the control of working conditions to ensure the protection of the safety and health of workers.

Environmental: the control of radiation to prevent damage to the environment and biosphere or to the health and welfare of man (non-occupational).

Additionally, there are programs concerned with authorizing spectrum use which do not originate, but include and implement, considerations and criteria for biological safety.

Other programs, not directly involving regulation, which contribute include those concerned with developing scientific knowledge; and mission oriented programs, which produce information needed to establish a better understanding of effects and meaningful definitions of safety.

The OTP research coordination activity has been primarily concerned with developing sound scientific knowledge upon which to base assessments of effects and definitions of exposure safety, and has not been directed to the regulatory process per se. However, the existence of this unique multiagency research program has played a considerable part in effecting a continuing dialogue between the regulatory organizations such as EPA, BRH, OSHA, etc.

OTP is concerned that any regulatory controls should be based on dependable scientific data and that there should be a consistent basis and logical rationale for standards in the aforementioned areas. Attention should also be given to risk, benefit considerations and cost/benefit where applicable (i.e. device emission standards).

Current scientific knowledge of electromagnetic radiation effects on man is not adequate to permit assessment of all possible risks, particularly for relatively low-level and long-term exposures. Known harmful effects can be caused by excessive heating, but concrete scientific evidence that harmful effects can be caused by other mechanisms of EMR interaction with biological systems is lacking.

The American National Standards Institute (ANSI) recommended a nonionizing radiation protection standard of 10 mW/cm^2 from 10 MHz to 100 GHz "to prevent possible harmful effects on mankind," based primarily upon thermal considerations. OSHA adopted this ANSI standard making it applicable to those exposed in the course of their employment (in 29 CFR 1910.17). It also applies to government employees through Executive Orders 11612 and 11807 which directed all Federal agencies to be consistent with all OSHA standards. The ANSI recommendation has not been applied to the general public by Federal action, although in practice it is widely used.

With regard to environmental standards for the general public (non-occupational), standard authorities are somewhat unclear. The establishment of EPA included the transfer of the authority of the former Federal Radiation Council, which did not specifically refer to nonionizing radiation. The EPA interprets this authority to include nonionizing radiation. There are other areas where regulatory and jurisdictional authorities are not entirely clear. Again, however, OTP's principal concern for any standard is that there be a rational basis for its issuance.

A different philosophy applies to the class of standards designed to control product emissions such as those pertaining to microwave ovens. They are intended to minimize all unnecessary radiation associated with a product, insofar as practicable, and are only indirectly related to human safety standards. It is interesting that, in terms of actual radiation in the environment, the oven standard is effectively more stringent than the guidelines recommended by ANSI, but this is due to the rationale for equipment emission standards. The failure to distinguish between emission and exposure can cause a misunderstanding of what is "safe" and a misunderstanding of the basis for a particular standard decision.

With regard to funding, the necessity for continuing research to develop an adequate basis for regulatory determinations must be underscored. This research requires expenditures greater than are presently being budgeted by the active research participants in the Federal program,. The program was structured to take advantage of existing responsibilities and capabilities. Agency mission and operational needs were viewed as incentives to utilize their technical capabilities to conduct research. However, nonionizing radiation must compete within each agency for priority and funding against many other research requirements, some with legimately higher mission or public interest importance.

While considerable research progress has been made, there remain many unanswered questions to date. However there are emerging clearer directions of research needs, many of which are very costly and would require a total or near-total investment of the currently budgeted resources of any single agency. Examples of these needs include studies involving long-term, chronic exposures, additional studies of basic mechanisms of interaction, studies of exposed people, and further development and refinement of dosimetry. A mechanism should be established to supplement the normal agency budgetary process in the ERM area to permit such work to be undertaken which would make effective use of the capabilities developed by the agencies involved. A rough estimate of required funding would be two to three times the present level of expenditure.

4. Any proposal to consolidate all Federal radiation activities into a single agency should give careful consideration to the tradeoffs involved.

It is important to ensure that reorganization along subject versus functional lines does not simply create additional bureaucracy, redundancy, and need for coordination with existing mission responsibilities of established agencies. The "consolidation of all radiation activities" implies that a single agency would be responsible for all aspects of radiation including all regulation (e.g. safety, environmental standards, devices, and radiation use), compliance, and enforcement, as well as research pertaining to safety and the development of new applications for use. Clearly this would overlap the established mission responsibilities of a number of agencies and require extensive reorganization to modify their missions to make exception for this one area. For example: Would DOL/

OSHA maintain its regulatory responsibility for occupational safety in all areas except radiation? Would an "Energy Agency" have responsibility for development, new technology and safety research, (and perhaps regulation) for all forms of energy except those involving ionizing or nonionizing radiation?

There is also the question of the desirability of having a single agency responsible for all radiation activities—research, use, and regulation. The former AEC had such a consolidated role for ionizing radiation and serious questions were raised as to whether this was desirable, based on the inherent conflicts between these functions. This resulted in reorganization in which the functions were dis-associated.

Other considerations include:

It is difficult to carry out sustained basic research in an agency which has regulatory responsibilities because the exigencies and demands of regulatory activities predominate. The requirement to develop standards and compliance and enforcement programs place heavy demands on limited resources—people facilities and budgets—often at the expense of biomedical research. Research tends to be constrained to the minimum necessary to support a standard and to be shifted from area to area (e.g., ionizing, light, microwave) as dictated by the business of standard setting. Generally, this places emphasis in areas with recognized problems and not on fundamental research needed to anticipate or determine whether a problem might exist.

The priorities established for research may not be responsive to the needs of other departments or agencies. For example, a unique, and mission critical, radiating system under development by one agency might be delayed pending research or authorization by the "consolidated" agency.

Research conducted only under the auspices of a single agency can lead to lack of flexibility in funding new approaches and possible loss of necessary research replication which can impair scientific credibility.

Consolidation or reorganization of research institutions can cause disruption, even a severe setback, to established research efforts. This was the case during the creation of the Environmental Protection Agency research program from within the resources of the Bureau of Radiological Health.

Consolidation could have some benefits such as better delineation of regulatory responsibilities and elimination of overlapping research requirements. However in view of the myriad of uses for radiation over the entire spectrum, it is unlikely that a consolidated agency could, in practice, eliminate all overlap or that it would be prudent to do so.

Department of Transportation,
Federal Aviation Administration,
Washington, D.C., June 1, 1977.

Hon. Wendell H. Ford
Chairman, Subcommittee on the Consumer, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Mr. Chairman: This is in further response to your letter of May 20 requesting information on Federal radiation, research, and regulatory programs.

At the outset, I should point out that the Federal Aviation Administration (FAA) has no regulatory powers with regard to either ionizing or nonionizing radiation. However, as one of the Federal Government's largest users of microwave producing equipment, we do have a considerable interest in radiation protection, both from the microwaves produced and the ionizing radiation associated with the production of such microwaves. We are also concerned with ionizing radiation from cosmic sources and nuclear testing and their effect upon the passengers of high altitude aircraft, such as the supersonic transport, and the ionizing radiation produced by isotopes which are transported in both commercial passenger and cargo aircraft.

In April 1967, the FAA formed an Advisory Committee on Radiation Biology Aspects of Supersonic Transport. This Committee consisted of 10 scientists who conducted studies on the biological aspects of cosmic radiation at altitudes to be flown by the SST. During its 8-year period of existence, the Committee met approximately 3 times annually and the results of their findings were reported to the Federal Air Surgeon at various intervals. The amount of money expended on this study was approximately $40,000 and the final report on SST operations was published in the September 1975 issue of Aviation Space and Environmental

Medicine. The Committee also drafted a report concerning cosmic radiation in subsonic flights at conventional altitudes which will be published before the end of 1977.

With the proposed construction of the American supersonic transport in 1968, we initiated a program at our Civil Aeromedical Institute in Oklahoma City, Oklahoma, to investigate the effects of cosmic and other types of ionizing radiation and their biological effects on passengers and crewmembers. Between the years 1968 and 1977, we expended a total of $855,000 in research funds and a total of 31 man years on such ionizing radiation studies. These studies consisted of exposing animals to various dosage rates of ionizing radiation and extrapolating the results to arrive at the possible biological effects upon human beings. As previously stated, these studies were carried on with relation to the possible biological effects of cosmic radiation on aircraft passengers aboard supersonic aircraft and similarly to determine the effects on passengers and crewmembers aboard subsonic aircraft transporting radioactive isotopes.

Since nuclear weapons test debris can result in possible contamination of civil aircraft, the FAA coordinates with other Federal agencies during such testing situations. In this regard, the Energy Research and Development Administration, pursuant to interagency agreement, is adapting their models to produce operational short-range and long-range forecasts of radioactive clouds in a format prescribed for FAA use in protecting the health and welfare of aircraft passengers and crews when nuclear weapons tests are conducted.

The FAA has 109 long-range radars, 159 short-range radars, and 930 VORTACs. All of these pieces of equipment, besides producing microwave, also produce ionizing radiation. Whenever more than 10,000 kilovolts are introduced into certain power tubes, x-radiation or ionizing radiation is an unwanted by-product which may affect the personnel operating such equipment. The FAA insists that all electron tubes producing such radiation be completely shielded and clearly marked in accordance with applicable safety regulations. The FAA also maintains a nucleus or industrial hygienists who monitor these locations with radiation detecting equipment to ensure that all safety regulations are met and that FAA personnel are properly safeguarded.

With regard to the microwave radiation produced by the previously mentioned equipment, the FAA insists that safety precautions are met. In the construction and installation of all microwave producing equipment, site selection is given the utmost consideration, particularly in the case of radars. Long-range radars which produce significant amounts of microwave radiation are mounted on 75-foot towers and primarily sited in remote areas. Careful consideration is given to siting to prevent human hazard, mechanical hazard, and possible pacemaker interference. In all cases, the protection of the public from exposure to such radiation is our primary consideration. Constant checks are made by FAA industrial hygienists to assure that operating personnel are completely protected from the hazards of microwave radiation.

To date, research into the effects of microwave radiation has been confined to a study of the microwave radiation produced by all types of FAA navigational facilities. This study was performed for the FAA by the National Bureau of Standards under a $250,000 contract extending over the years 1973, 1974, and 1975. This particular study was authorized by Secretary Volpe at the request of the Office of Telecommunication Policy. The purpose of this study was to determine the actual amounts of microwave radiation produced by all of the various FAA navigational equipment and to give the FAA an indication of what, if any, hazards existed and what remedial action might be needed. We have also instituted a study to determine the effects of microwave radiation on human health. This study is to begin in fiscal year 1978 and is presently funded at $24,500. We have already started to interview other Federal agencies with regard to their human effects research and we are considering studying the effect of chromosome changes in irradiated tissue as it is a known fact that where cancer is involved, chromosomal changes are always noted.

As previously noted, the FAA is concerned with the carriage aboard aircraft of radioactive materials, and prior to the enactment of the Transportation Safety Act of 1974 (Public Law 93–633), the FAA was responsible for prescribing regulations governing the air transportation of hazardous materials. Pursuant to this Act, the Department of Transportation's Materials Transportation Bureau (MTB) assumed authority on July 7, 1975, for promulgating regulations governing the carriage of hazardous materials by all modes of transportation.

The FAA's present responsibilities in this area now consist of coordination with MTB on regulatory matters and surveillance and enforcement activities.

A summation of the in-house positions, extra-mural funds, and total funds for FAA activities is contained in the enclosed matrices. We note that the funds listed on the enclosed charts represent our best estimates of total costs but may not be precise due to the limited time available to compile these data. Also, the figures shown for transportation of hazardous materials reflect all forms of hazardous materials and are not available respecting radioactive materials alone.

With respect to the questions posed in your letter, we offer the following comments:

1. The passage of the Occupational Safety and Health Act of 1970 has had a profound effect upon our agency's responsibilities with regard to radiation hazards. The rules regarding the protection of agency employees are requiring the annual inspection of those facilities which produce either ionizing radiation or microwave radiation, or both. This has placed an unusual workload upon our industrial hygienists and may require additional personnel in order that we may conduct the inspections necessary to comply with the Act.

Additionally, as noted in the body of our letter, subsequent to the enactment of the Transportation Safety Act of 1974, our regulatory authority for air transportation of hazardous materials (including radioactive materials) was assumed by the Materials Transportation Bureau. The FAA still retains surveillance and enforcement responsibilities. We understand that MTB is also providing information to the Committee which will expand on their specific responsibilities.

2. We are not required to contact or coordinate with State agencies and we have never discerned any confusion as to respective responsibilities.

3. We believe that the present regulation of radiation programs could be improved by assuring that all agencies involved in radiation programs are using the same methods to arrive at final determinations. Specifically, we believe that the methods of measuring the amounts of radiation produced in both the ionizing and non-ionizing spectrum should be clearly defined. In other words, the method of measuring, and the equipment used, should be standardized to assure that results obtained by different agencies are consistent. We do not have adequate information to satisfactorily address the issue of present funding levels in the areas of research and instrumentation on a government-wide basis.

4. While the consolidation of radiation activities into one Federal agency would certainly make coordination on radiation matters much simpler, we are not prepared at this time to advocate the institution of such an agency. We believe there are a number of variables which need to be carefully examined; for example, the extent to which various agencies can presently apply their specific areas of expertise to radiation-related matters affecting their agency programs should be considered.

Thank you for providing the FAA the opportunity to offer our views on these matters. We will be pleased to work with your Subcommittee's staff if additional information is needed.

Sincerely,

BRUCE SELFON.

Enclosure.

IONIZING RADIATION

Civil Aeromedical Institute Study

Advisory Committee

Energy Research and Development Administration Agreement

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)	3 NONE $47,500						.6 NONE $8,000				10 NONE $5,000	
1969 Extra-Mural (Funds) ~~Total Funds~~	3 NONE $50,000						.6 NONE $9,200				10 NONE $5,000	
1970	3 NONE $51,500						.6 NONE $10,300				10 NONE $5,000	
1971	3 NONE $55,500						.6 NONE $11,800				10 NONE $5,000	
1972	3 NONE $56,000						.6 NONE $13,600				10 NONE $5,000	
1973	3 NONE $66,400						.6 NONE $14,500				10 NONE $5,000	
1974	3 NONE $86,100						.6 NONE $15,900				10 NONE $5,000	
1975	3 NONE $109,300						.6 NONE $17,500					
1976	3 NONE $119,800						.6 NONE $18,700					
1977	4 NONE $110,230						.6 NONE $20,500					.2 NONE $80,000
Est. 978	3 NONE $96,000						.6 NONE $22,000					.1 NONE $2,500

applies to all years

IONIZING RADIATION

ACTIVITIES REGARDING TRANSPORTATION OF HAZARDOUS MATERIALS

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)							8 NONE $500, 000					
1969 Extra-Mural (Funds) Total Funds							8 NONE $500, 000					
1970							8 NONE $500, 000					
1971							8 NONE $500, 000					
1972							8 NONE $500, 000					
1973							8 NONE $500, 000					
1974							34 NONE $500, 000					
1975							38 NONE $460, 000					
1976							64 NONE $1, 200, 000					
1977							58 NONE $1, 000, 000					
Est. 1978							58 NONE $1, 000 000					

applies to all years

NON-IONIZING RADIATION*
MICROWAVE

Microwave Radiation Study

National Bureau of Standards Contract

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 -In-House (Positions)							.9 NONE $12,000					
1969 -Extra-Mural (Funds) -Total Funds							.9 NONE $13,600					
1970							.9 NONE $15,100					
1971							.9 NONE $17,800					
1972							.9 NONE $19,900					
1973							.9 NONE $22,000			0 $50,000 $50,000		
1974							.9 NONE $24,500			0 $100,000 $100,000		
1975							.9 NONE $26,000			0 $100,000 $100,000		
1976							.9 NONE $28,500					
1977							.9 NONE $30,200					
Est. 1978	.6 NONE $24,500						.9 NONE $33,000					

Department of Transportation,
Materials Transportation Bureau,
Washington, D.C., June 22, 1977.

Hon. Adlai E. Stevenson,
Chairman, Subcommittee on Science, Technology, and Space, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Senator Stevenson: Thank you for your and Senator Wendell H. Ford's letter of May 20, 1977. The matrix form for ionizing radiation has been completed as it pertains to the programs of the Materials Transportation Bureau relative to ionizing radiation. There are no relevant programs in the nonionizing radiation area.

With regard to the specific questions in your letter, we offer the following:

1. The major change in Federal jurisdictions between 1968 and 1977 which has affected this Bureau was the formation of the U.S. Nuclear Regulatory Commission (NRC) and the Energy Research and Development Administration (ERDA), as a result of the Energy Reorganization Act of 1974 which disestablished the U.S. Atomic Energy Commission (AEC). Whereas our liaison on matters relating to regulation of the safe transport of radioactive materials was principally with the AEC, it now is with the NRC. The March 22, 1973, Atomic Energy Commission/Department of Transportation (DOT) Memorandum of Understanding (copy enclosed) is currently being updated between DOT and NRC.

2. The contacts between the MTB and state groups pertain solely to matters relating to the regulations for the safe transport of radioactive materials. These contacts involve questions on the interface of Federal versus state regulatory programs for safe transport of hazardous and radioactive materials, enforcement and compliance questions, and training and planning for handling of transportation emergencies. Due to the provisions of Section 112 of Public Law 93–633, the Transportation Safety Act of 1974, contacts with the states are increasing relative to the effect of state regulation on Federal regulations and possible preemption of inconsistent state regulations.

3. The present radiation regulatory programs could be improved by amending the Atomic Energy Act to include the regulation of machine-produced radioactive materials, in addition to the by-product, source, and special nuclear materials now regulated by NRC. We note that in its "agreement state" programs, the NRC requires that the state's jurisdiction include all forms of radioactive materials. Such consistency should be added to the NRC's authority in regulating its "non-agreement" state licensees.

4. The proposals to consolidate all Federal radiation activities into one Federal radiation agency are, in our opinion, oversimplistic. In the area of transportation, if this were done (i.e., selecting one type of hazardous material for separate regulation), a logical follow-on would suggest that separate Federal agencies be established for consolidated Federal regulation of all aspects of explosives, flammables, corrosives, toxic materials, etiologic agents, etc.

It is our feeling, therefore, that consolidation of all Federal regulatory authority into a single agency would be counterproductive to the total regulatory system.

Sincerely,

John Fearnsides
(For Alan A. Butchman, Acting Director).

Enclosures.

Further Descriptions to Table Entries

The programs involving radiation regulations are principally focused on the regulation of the transportation of hazardous materials in interstate and foreign commerce. Radioactive materials are one of the major classes of regulated hazardous materials. Two areas as listed on the matrix for ionizing radiation are:

CRITERIA AND/OR STANDARDS DEVELOPMENT

This effort involves the development and promulgation of amendments to the Department's Hazardous Materials Regulations in 49 CFR, Parts 100–199, as they affect transport of radioactive materials. Close coordination of this effort is maintained with the U.S. Nuclear Regulatory Commission and prior to 1975 with its predecessor agency, the U.S. Atomic Energy Commission. Due to statutory overlap in jurisdiction, each agency operates under a written DOT/AEC Memorandum of Understanding (copy enclosed in letter), which is currently in the process of being updated between DOT and NRC.

STATE/FEDERAL LIAISON

In addition to frequent liaison with the U.S. NRC, liaison is carried out with several other Federal agencies, including ERDA, EPA and HEW (Bureau of Radiological Health) on matters relating to radiation safety in transportation.

With respect to individual states, increasing liaison is carried out on matters relating to regulations enforcement, compliance, and accident reporting for radioactive materials. Additionally, liaison is increasing on matters relating to adoption of regulations by states and the possible impact of Section 112 of the Transportation Safety Act of 1974 (Public Law 93–633), dealing with preemption of Federal regulations.

IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)				1.0 m/y	0.5 m/y							
1969 Extra-Mural (Funds) ~~Total Funds~~				1.0 m/y	0.5 m/y							
1970				0.7 m/y	0.5 m/y							
1971				0.7 m/y	0.3 m/y							
1972				1.0 m/y	0.5 m/y							
1973				1.0 m/y	0.5 m/y							
1974				1.0 m/y	0.5 m/y							
1975				1.0 m/y	0.5 m/y							
1976				1.0 m/y	0.5 m/y							
1977				1.3 m/y	0.7 m/y							
Est. 1978												

applies to all years

MEMORANDUM OF UNDERSTANDING BETWEEN THE UNITED STATES DEPARTMENT OF TRANSPORTATION AND THE UNITED STATES ATOMIC ENERGY COMMISSION

For Regulation of Safety in the Transportation of Radioactive Materials Under The Jurisdiction of the Department of Transportation and the Atomic Energy Commission

The Department of Trasportation (DOT, under the Transportation of Explosives Act (18, U.S.C. §§ 831–835), the Dangerous Cargo Act (R.S. 4472, as amended, 46 U.S.C. 170), and Title VI and § 902(h) of the Federal Aviation Act of 1958 (49 U.S.C. 1421–1430 and 1472(h)), is authorized to regulate the transportation of explosives and other dangerous articles, including radioactive materials. The Atomic Energy Commission (AEC), under 42 U.S.C. Chapter 23, is authorized to license and regulate the receipt, possession, use and transfer of "by-product material," "source material," and "special nuclear material." The AEC, through appropriate contractual provisions as implemented by AEC Manual requirements and specific instruction, also controls the receipt, possession, use, and transfer of radioactive material by those AEC contractors who are exempt from AEC licensing requirements.

For the purpose of developing, establishing, and implementing consistent and comprehensive regulations and requirements for the safe transportation of radioactive materials, and avoiding duplication of efforts, DOT and AEC agree, subject to their respective statutory authorities, as follows:

I. DEVELOPMENT OF STANDARDS

A. DOT will develop safety standards governing all radioactive material packings and their contents, and the classification, labeling and marketing of all radioactive material packages, except for those types of radioactive material and areas of technical competence specified in paragraph B.

B. AEC will develop safety standards, for packaging design and performance, for packages of fissile materials and Type B and large quantities of radioactive material in the following areas: (1) Structural materials of fabrication; (2) Closure devices; (3) Structural integrity; (4) Criticality control; (5) Containment of radioactive material; (6) Shielding retention; (7) Generation of internal pressure; (8) Internal contamination; (9) Protection against internal overheating; and (10) Quality control of packaging fabrication and continued use.

C. DOT will deveolp safety standards governing mechanical conditions of carrier equipment and qualifications of carrier personnel, carrier loading, unloading, handling and storage of radioactive material, and any special transport controls to be provided during carriage, including construction standards for transport vehicles.

II. REGULATIONS

A. DOT will adopt regulations imposing, on shippers and carriers subject to its jurisdiction, those standards developed by AEC and DOT pursuant to Section I of this memorandum, and will adopt a requirement for AEC approval of packages for shipment of fissile material, and Type B and large quantities of radioactive material by all persons not otherwise subject to the provisions of 10 CFR Part 71 or AEC Manual requirements, but subject to DOT jurisdiction.

B. AEC will adopt regulations and contractual requirements imposing, on AEC licensees and license-exempt contractors, those standards which it has developed pursuant to Section I, and procedures and criteria for approval of proposed package designs and transport controls peculiar to the package design, and will require that AEC licensees and license-exempt contractors comply with the applicable requirements of DOT regulations when transporting or shipping radioactive material, when those persons are not otherwise subject to the provisions of DOT regulations.

III. PACKAGE REVIEW

A. AEC will evaluate package designs for fissile material and Type B and large quantities of radioactive material, and will, if satisfactory, issue approvals therefore (i.e., an AEC license, and AEC certificate of compliance, or other AEC package approval) directly to the person requesting the evaluation.

B. AEC will evaluate package designs for specification containers and will make appropriate recommendations to the DOT for its consideration.

C. With respect to those designs of packages intended to be used for transporting radioactive material in the United States, which have been approved by foreign competent national authorities but which require revalidation under DOT regulations, DOT will submit to AEC for approval those designs of packages (1) for Type B quantities where, in DOT's opinion, evaluation by AEC is warranted, (2) for fissile material, and (3) for large quantities of radioactive materials.

IV. INSPECTION AND ENFORCEMENT

A. Each agency will conduct an inspection and enforcement program within its jurisdiction, to assure compliance with its requirements.

B. DOT and AEC will consult with each other on the results of their inspections, and each will take enforcement action as it deems appropriate within the limits of its authority.

V. ACCIDENTS AND INCIDENTS

A. DOT will require notification and reporting of accidents, incidents, or suspected leakage involving radioactive material packages if such occurs or is discovered while in transit. When such cases occur during transit, DOT will be the lead agency[1] in investigation of the occurrence and in preparation of the report of the investigation.

B. AEC will require notification and reporting of accidents, incidents, and suspected leakage involving radioactive material packages if such occurs or is discovered prior to delivery of the radioactive material packages to a carrier for transport or after delivery to a receiver. When such cases occur other than during transit, AEC will be the lead agency[1] in investigation of the occurrence and in preparation of the report of the investigation.

C. Notwithstanding paragraphs A & B, this section V. does not affect the authority of the National Transportation Safety Board.

VI. NATIONAL COMPETENT AUTHORITY

A. DOT will be the national competent authority with respect to the administrative requirements set forth in the Regulations for the Safe Transport of Radioactive Materials of the International Atomic Energy Agency. In issuing certificates of national competent authority for the United States under those regulations, DOT will require, for containers other than DOT specification containers, an AEC certificate of approval or a showing that the shipment is within the scope of an exemption or general license under 10 CFR Part 71 or AEC Manual Chapter.

B. DOT will act as the representative of the United States to the International Atomic Energy Agency and other international groups on matters pertaining to transportation of radioactive material. AEC will provide technical support and advice to DOT in this area.

VII. EXCHANGE OF INFORMATION

A. Prior to issuance of any regulations by either DOT or AEC involving transportation of radioactive materials, each agency will advise and consult with the other to avoid possible conflict in the regulations and to assure that: (1) the regulations are in the public interest; (2) the regulations are in accord with the best-known, practicable means of providing safety in transportation; (3) the effect of these regulations will not be inimical to the common defense and security of the United States; and (4) the regulations will not constitute an unreasonable risk to the health and safety of the public.

B. DOT and AEC will exchange information, consult with, and assist each other within the areas of their special competence in the development and enforcement of regulations and requirements. Each agency will make available to the other, subject to security requirements and statutory provisions affecting the release of information, summaries of inspection records, investigations of serious accidents and other matters relating to safety in the transportation of radioactive materials.

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[1] The lead agency has primary responsibility for investigating the occurrence and preparing the report of the investigation. The other agency may participate in the investigation with the lead agency or conduct a separate investigation if it chooses to do so.

VIII. WORKING ARRANGEMENTS

A. AEC and DOT will designate appropriate staff representatives and will establish joint working arrangements from time to time for the purpose of administering this Memorandum of Understanding.

IX. GENERAL

A. Nothing herein is intended to affect the statutory exemption of shipments of radioactive materials made by or under the direction or supervision of the AEC or Department of Defense in accordance with the provisions of 18 U.S.C. § 832(c).

B. This agreement shall take effect upon the signing by authorized representatives of the respective agencies, and shall supersede in its entirety the March 21, 1966, Memorandum of Understanding between the ICC and AEC.

C. Nothing in this Memorandum is intended to restrict the statutory authority of either agency.

Done at Washington, D.C., in triplicate, this — day of March 1973.

For the U.S. Department of Transportation:

CLAUDE S. BRINEGAR,
Secretary,

For the U.S. Atomic Energy Commission:

DIXY LEE RAY,
Chairman.

DEPARTMENT OF TRANSPORTATION,
U.S. COAST GUARD,
Washington, D.C., July 18, 1977.

Hon. WENDELL H. FORD,
Chairman, Consumer Subcommittee, Committee on Commerce, Scicnce, and Transportation, U.S. Senate, Washington, D.C.

DEAR SENATOR FORD: This is in response to your letter of May 20, 1977, regarding federal responsibilities in the areas of radiation health and safety research and regulation. The completed matrices concerning involvement in radiation regulatory and research programs for ionizing and nonionizing radiation are forwarded as enclosures (1) and (2) respectively. With regard to the four specific questions posed in your letter the following responses are offered:

1. In 1975 a new Bureau, the Materials Transportation Bureau, was formed within the Department of Transportation. This Bureau was delegated the regulatory authority, formerly vested in the modal administrations, regarding the transport of packaged hazardous materials, including radioactive materials. This action consolidated the packaged hazardous materials regulatory authority in a single agency. The result of centralizing this authority in one Bureau has the effect of decentralizing the authority of the modal administrations to regulate all aspects of transport in their particular mode. Therefore, as a result of the establishment of the Materials Transportation Bureau in 1975, the Coast Guard is no longer responsible for issuance of regulations governing the transport of radioactive materials by vessel. However, responsibility for enforcement of these regulations remains with the Coast Guard.

2. Since the Coast Guard is now only responsible for the enforcement of federal regulations governing the transportation of radioactive materials by vessel, there is little need for coordination and contact with state agencies. There has been no confusion concerning the respective responsibilities of the Coast Guard and state agencies in this area.

3. The Coast Guard's involvement in the regulation of radioactive materials is rather limited. I am, therefore, unable to offer suggestions regarding improvement of the overall system of regulations of these materials. Funding for the Coast Guard's role of enforcement of the regulations governing transportation of radioactive materials by vessel is considered adequate.

4. I believe that great care should be taken in, and careful consideration given to, consolidating all federal radiation activities into one federal radiation agency. In general, the task of setting basic standards for radiation regulation can be assigned to a single agency. However, implementing regulations requiring specialized expertise in other areas should rest within those agencies having that expertise. For example, in the transportation of radioactive material by vessel, while it is logical that the basic standards should be set by the agency with the greatest technical expertise, the implementation of these standards should be carried out by the Coast Guard, the agency having the expertise in the overall area of marine safety.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

O. W. SILER,
Admiral, U.S. Coast Guard, Commandant.

IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)				1 Position(½ manyr) 0 Extra Mural Funding $8000 Total Funding			650 Position (manyears)* 0 Extramural Funds **					
1969 Extra-Mural (Funds) Total Funds				1(½) 0 $8000			650(*) 0 **					
1970				1(½) 0 $8000			650(*) 0 **					
1971				1(½) 0 $8000			650(*) 0 **					
1972				1(½) 0 $8000			650(*) 0 **					
1973				1(½) 0 $8000			650(*) 0 **					
1974				1(½) 0 $8000			650(0.3) 0 $3000					
1975				1(¼) 0 $4000			650(0.4) 0 $4000					
1976				1(¼) 0 $4000			650(0.3) 0 $3000					
1977				1(¼) 0 $4000			650(*) 0 **					
Est. 1978				1(¼) 0 $4000			650(*) 0 $4000					

applies to all years

*Actual manyears involved unknown
** Actual cost unknown

ENCLOSURE (1)

NON-IONIZING RADIATION*

*(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing; Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)												
1969 Extra-Mural (Funds) Total Funds												
1970			The Coast Guard has had no involvement in the regulation of nonionizing radiation. No studies concerning the health and safety effects of normal radio or navigational transmissions were conducted.									
1971*												
1972												
1973												
1974												
1975												
1976												
1977												
Est. 1978												

applies to all years

ENCLOSURE (2)

VETERANS ADMINISTRATION,
Washington, D.C., July 1, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: I am pleased to respond to your letter of June 9 in regard to the comprehensive hearings of the Senate Committee on Commerce, Science, and Transportation concerning review and evaluation of federal radiation research and regulatory programs.

With respect to the questions posed in your letter, we offer these comments:

1. Reorganization Plan No. 3 of 1970, creating the Environmental Protection Agency, has led to close cooperation between the Veterans Administration, and this new agency. For example, three members of the Veterans Administration Central Office participated in the activities of the Environmental Protection Agency Subcommittee which produced the background report, "Recommendations on Guidance for Diagnostic X-Ray Studies in Federal Health Care Facilities."

The Occupational Safety & Health Act of 1970 has resulted in the proliferation of reporting requirements.

Public Law 93–438, the Energy Reorganization Act of 1974 transferred our licensing for the use of spontaneously ionizing material, and site inspections pertaining to their use, from the Atomic Energy Commission to the Nuclear Regulatory Commission on January 19, 1975. The close, cordial, cooperative liaison that the Veterans Administration enjoyed with the now defunct Atomic Energy Commission, has continued and been expanded.

Public Law 93–633, Transportation Safety Act of 1974, making the Federal Aviation Administration responsible for prescribing regulations governing air transportation of hazardous materials, resulted initially in concern that delivery of the radionuclides used in medicine might be impeded. However, interpretation of the law has dispelled this concern.

The changes in jurisdiction described have multiplied our reporting activities.

2. We are not required to contact or coordinate with state agencies, and we have not perceived any confusion as to respective responsibilities of state and federal agencies.

3. We believe that the present regulation of radiation programs could be improved by requiring that all agencies involved in radiation programs use the same standards for measuring both ionizing and nonionizing radiation, and for calibration of equipment. These standards should be clearly defined. We do not have the data necessary to give an informed response on the subject of the adequacy of current government-wide funding levels in radiation regulation.

4. Our reaction to proposals to consolidate all federal radiation activities into one federal radiation agency is that, although there are attractive features to the single agency concept, so many diverse considerations are involved in this matter, that careful in-depth examinations into the subject should be made before any decision is reached.

We have condensed your matrix, using only those columns which apply to Veterans Administration activities. There is no information to report prior to 1972.

We do not have the data to furnish a description of each project and its cost. Our listing of positions, and funds expended, incorporate programs in all the categories listed in the heading of the matrix summary enclosure.

Thank you for providing the Veterans Administration the opportunity to offer our views on these matters. We shall be pleased to work with the Staff of your Committee if additional information is needed.

Sincerely,

RUFUS H. WILSON,
Deputy Administrator,
(For Max Cleland, Administrator).

Enclosure.

VETERANS ADMINISTRATION

NON-IONIZING RADIATION

Ultrasound, Microwave, Radiofrequency
Ultraviolet, Visible Light, Infrared

Year	Studies to determine human health effects	Monitoring &/or Surveillance	Medical Diagnostic Therapeutic	Other biological or physical effects studies
1972 In-House (Positions)				1.0 None $ 39,657
1973 --Extra-Mural (Funds) --Total Funds				2.0 $ 38,049 $119,276
1974				2.0 $ 48,489 $134,308
1975				2.0 $ 40,183 $124,792
1976	3.0 $ 61,940 $139,972	0 $ 8,692 $ 8,692	22.0 $123,067 $710,767	8.0 $ 45,239 $154,311
1977	3.0 $ 31,201 $110,960	0 $ 5,000 $ 5,000	22.0 $147,356 $736,210	9.0 $850,695 $166,997
Est. 1978	3.0 $ 28,000 $108,000	0 $ 4,500 $ 4,500	22.0 $150,000. $740,000	10.0 $ 54,116 $174,116

applies to all years

U.S. Department of Commerce,
National Bureau of Standards,
Washington, D.C., June 7, 1977.

Senator Adlai E. Stevenson,
Chairman, Science, Technology, and Space Subcommittee, Committee on Commerce, Science, and Transportation U.S. Senate, Washington, D.C.

Dear Senator Stevenson: This is in response to your letter, co-signed with Senator Wendell H. Ford, dated May 20, 1977, which requested information about projects or programs relevant to radiation health and safety research and regulation. This same letter is also being sent to Senator Ford.

The comprehensive listing and short description of appropriate NBS activities is attached, utilizing the format of the suggested matrices. Although the brief categorizations of studies as indicated by the column headings may have been misinterpreted by us, that should become evident from the accompany descriptions and enable necessary adjustments.

Your letter requested written response to four specific questions. Our reply to each question follows.

(1) The significant changes in jurisdiction since 1968 were the Radiation Control for Health and Safety Act (1968), Reorganization Plan #3 (1970), and the Occupational Safety and Health Act (1970). Although its impact on NBS is not yet clear, the Medical Devices Amendment to the Food, Drug, and Cosmetic Act (1976) is expected to be significant in that regard. The effect of these changes in jurisdiction has been largely due to the inception of new regulations, rather than the result of transfers of regulatory authority.

By its organic legislation, NBS responsibilities include the development and maintenance of the physical standards of measurement and the provision of means throughout the country for their effective use. NBS is also charged with the responsibility of providing assistance to other agencies in their needs for measurements, standards, and essential technical data. Because enforcement of regulations is frequently based on measurements, the effect on NBS has been substantial. Expanded activities become necessary to provide the measurement standards, instruments, and measurement quality assurance needed to support new regulations. These services from NBS are needed both by the regulators and by those who are regulated.

Thus, the promulgation of new regulations to protect the public safety in ionizing radiation and in diverse areas of non-ionizing radiations such as ultrasonic radiation, rf and microwave radiation, ultraviolet radiation, and laser radiation have required new efforts by NBS to ensure that adequate measurement standards, and measurement techniques are developed.

In addition to measurement and standards needs to directly support present regulatory actions, improvement in technology or potential new hazards to public safety have required NBS actions. For example, it is now widely accepted that effective cancer radiation therapy requires radiation dosimetry measurements which are accurate to 5 percent or better, yet many treatment centers do not routinely achieve such accuracy. Through measurement assurance testing programs, NBS is attempting to improve this situation. Similarly, the possibility that atmospheric modification by freons and other man-made substances will result in change in the UV transmission of the atmosphere has stimulated NBS efforts to develop improved UV measurement techniques and standards required for accurate long-term monitoring of these possible effects.

These many new needs for NBS services have seriously strained our ability to respond in a proper and timely manner.

(2) During the past few years, contacts between NBS and state radiation control programs has increased substantially. Beginning in 1975, NBS surveyed measurement needs and capabilities in state ionizing radiation programs. The Conference of Radiation Control Program Directors created a special task force to cooperate with NBS during and after the survey. At this time, several pilot programs are being initiated to provide needed services to state programs, thereby assuring that measurements made in those programs will be sufficently accurate and reliable. This is particularly important since the ultimate responsibility for protection of the public from radiation hazards rests in the state programs.

The National Bureau of Standards is required to provide services to state governments, but is not specifically required to contact or coordinate with state agencies. However, to use limited resources effectively and efficiently coordination and contact such as that described above is generally advisable. This is consistent with the President's recently expressed desire to involve state officials in the development of federal programs which have state impact.

There is some confusion about respective responsibilities of state and federal regulatory agencies. The variety of possible agreements, contracts, and preemptions adds to this confusion. In addition, many regulations at the federal and state levels have boundaries or limitations which are not immediately obvious. Some apply only to manufacture and distribution of a product or device; others also include control over use. In some cases, state regulations are applicable in general areas where no federal regulations exist. The confusion is compounded because of the several federal agencies involved and the sometimes apparent duplication of jurisdiction and inadequate coordination between federal agencies.

(3) At present, federal regulatory authority allows adequate provision for control of the manufacturers of radiation producing devices and for the protection of radiation workers who might be exposed to radiations from these devices. However, federal authority to regulate how these devices are used is unclear. This is particularly true in the healing arts. Thus, for example, although it is clearly a medical decision as to how much radiation dose a patient should receive in a cancer therapy treatment, the question of whether the prescribed dose was actually delivered is not a medical decision. Considerable evidence exists from measurement assurance testing done by NBS and by others that the prescribed dose is often not delivered with adequate accuracy. Federal regulatory authority to require adequate measurement quality assurance is unclear.

Similarly, no clear federal regulatory authority exists regarding naturally occurring radioactive substances.

For practical reasons, the state radiation control programs have responsibility for enforcing most of the regulations promulgated by both federal and state agencies. In spite of this major responsibility for public safety and health, state programs are generally understaffed, underpaid, lack adequate equipment, and often have inadequately trained staff. In many instances, the diversity of federal regulations and regulatory agencies compounds the problems. Measures should be taken to provide more support to state programs and to eliminate practices that hamper their efficiency.

From the NBS viewpoint, the deficiencies which deserve priority attention in present regulations are the lack of explicit requirements for measurement accuracy. Although enforcement of most regulations depends on measurements which are defendable in court, very few measurements would pass that test. The primary reason is the lack of assured high quality in regulatory measurements. Such quality could be achieved through measurement assurance programs which would require periodic calibrations of instruments and tests of performance. Prescribed methods could be required to achieve meaningful traceability to national measurement standards maintained by NBS. Closer cooperation between NBS and the regulatory agencies is necessary to achieve this goal. Such actions are being initiated by NBS.

As mentioned above, funding of state radiation control programs is generally inadequate. This is also true of federal agencies. For NBS, resources at present are inadequate to develop all of the needed measurement standards in both ionizing and non-ionizing radiation on a proper time scale to support regulatory needs, or to provide adequately the measurement assistance needed by state regulators, by industry, and by researchers involved in developing the data base for radiation regulations.

(4) At its 5th annual meeting in May 1973, the Conference of Radiation Control Program Directors passed a resolution to "urge the Congress of the United States to consider this serious problem of fragmentation and take the necessary legislative action to consolidate the various federal responsibilities relating to radiation protection of the public and worker within one agency." The reasons for the resolution were stated as "duplication, inefficiency, contradictions, and complexities in communication." These continue to be valid reasons why consolidation of federal regulatory activities might be desirable.

The responsibilities of NBS in providing measurement support for regulatory programs could be fulfilled more efficiently and effectively if interactions were required with only one federal regulatory agency. At this time, appreciable effort is expended in coordination of activities with the various agencies, and serving as a communications link or referee among them.

Despite these advantages of a single federal agency responsible for radiation regulation, we believe any such consolidation into a single agency should be taken very cautiously. Some obvious areas of overlapping responsibilities among agencies should be corrected, and some degree of consolidation would be desirable. However, one single agency responsible for federal regulation of ionizing and non-ionizing radiation, radiation safety in nuclear power development, radiation safety in medical practice, environmental radiation both ionizing and non-ionizing, etc., could become very large and difficult to manage, could have substantial internal conflicts of interest, and would find it difficult to achieve adequate communications with the communities they must regulate. Better results might be achieved by taking steps to ensure that adequate communications, cooperation and planning exists between existing federal regulatory agencies.

I hope this response will be useful in the forthcoming deliberations of the Senate Committee on Commerce, Science, and Transportation. If there is any additional information that I, or members of my staff, can provide, please feel free to call upon us. Thank you for the opportunity to comment on this important subject.

Sincerely,

ERNEST AMBLER,
Acting Director.

Enclosures.

Ionizing Radiation

Year	Studies to determine human health effects	Ecological efforts, animal/plant	Agricultural effects, plant/animal	Criteria and/or standards development	State/Federal liaison	Licensing, certification, inspection	Monitoring and/or surveillance	Medical, diagnostic, therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain)	Other studies (explain)
1968:												
In-house (positions)				2			4	11			2	5
Extramural (funds)				0			52	140			68	118
Total funds				70			116	303			68	118
1969:												
In-house (positions)				2			4	15			2	4
Extramural (funds)				0			55	97			65	124
Total funds				80			115	558			65	124
1970:												
In-house (positions)				2			3	14			2	4
Extramural (funds)				0			73	81			71	127
Total funds				90			145	533			93	127
1971:												
In-house (positions)				2			6	14			2	4
Extramural (funds)				0			168	94			57	113
Total funds				90			268	616			117	113
1972;												
In-house (positions)				2			7	10			2	4
Extramural (funds)				0			173	0			58	151
Total funds				100			359	461			117	151
1973:												
In-house (positions)				2			8	11			2	3
Extramural (funds)				0			190	50			56	135
Total funds				110			403	588			112	135
1974:												
In-house (positions)				3			8	12			3	3
Extramural (funds)				15			55	125			57	140
Total funds				135			372	646			158	140
1975:												
In-house (positions)				3	2		11	12			3	3
Extramural (funds)				0	0		56	142			59	146
Total funds				130	90		516	643			183	146
1976:												
In-house (positions)				4	3		12	12			3	3
Extramural (funds)				25	0		133	167			62	155
Total funds				160	215		632	714			178	155
1977:												
In-house (positions)				4	3		11	13			3	2
Extramural				0	0		167	187			81	116
Total funds				180	225		626	775			202	116
1978 estimate:												
In-house (positions)				4	3		12	13			3	2
Extramural (funds)				50	0		200	210			90	125
Total funds				220	250		660	740			210	125

DESCRIPTION OF NBS PROGRAM

IONIZING RADIATION

NOTE. (1) Funds in thousands of dollars. (2) Extra-mural funds are those obtained from other agencies to support NBS in-house programs. (3) Total funds include support from other agencies and support from the NBS appropriation.

Criteria and/or standards development

Although NBS is a non-regulatory agency it provides input to criteria and standards, particularly with respect to measurement and instrumentation aspects. In addition, significant effort is devoted to providing input to the development of voluntary standards which may themselves be adopted and enforced by regulatory agencies at various levels, or may influence future legislation. Two examples follow.

The goal of one activity is to improve the reliability of the performance of the suppliers of personnel monitoring services in the United States. In cooperation with the BRH and NRC, criteria are being developed for testing the performance of the suppliers on a continuing basis. Due largely to NBS efforts, the pertinent regulatory agencies will be able to require compulsory testing of suppliers of personnel dosimetry services by the year 1979 or earlier. On November 30 and December 1, 1976, joint public hearings were held by the BRH, NRC, and ERDA regarding proposed rulemaking in this field. NBS is also providing leadership of an ad hoc interagency policy committee whose purpose is to ensure that actions of relevant federal and state regulatory bodies are adequately coordinated in this effort.

American National Standards Committee N43 is concerned with standards for equipment used in non-medical radiation applications. NBS serves as the secretariat and provides the chairman of this committee. BRH and the NRC are heavily represented on the N43 subcommittees which produce the voluntary standards published as NBS Handbooks. If an effective voluntary standard exists, regulations may be unnecessary or may refer to the voluntary standard. BRH is particularly interested in a forthcoming N43 standard on industrial x-ray equipment, and will cooperate in the production of a standard for electron microscopes.

State/Federal liaison

The Conference of Radiation Control Program Directors consists of a representative from each state and territorial radiation control program. It began with a meeting which was called to discuss federal-state implementation of the Radiation Control for Health and Safety Act of 1968. The CRCPD is now jointly sponsored by the BRH, NRC, EPA, and NBS. The annual meeting of the group is called the National Conference on Radiation Control. NBS radiation measurement assurance programs were described in a paper presented by an NBS staff member at the 1976 annual meeting.

NBS has initiated a program to assist the states in improving the quality of measurements made for enforcement of regulations which provide radiation safety for the public. Through contracts and agreements, the states have ultimate responsibility for enforcing federal regulations in addition to state regulations. Some of the work of the NBS program wil be accomplished through task forces created by the Conference of Radiation Control Program Directors. These task forces consist of representatives from the states and interested federal agencies.

Monitoring and/or surveillance

This effort is directed toward providing the national reference for measurements made to detect radioactivity in the environment. Included are radioactive contamination from nuclear explosions resulting in fallout, and effluents from power reactors. NBS produces and distributes well-characterized sources of radioactive materials which are used to calibrate measurement systems used in the field. In addition, NBS cooperates with other agencies in providing services necessary to improve the quality of field measurements. Since 1971, a program sponsored by the Nuclear Regulatory Commission has had the general purpose of improving the accuracy and reliability of measurements of environmental radioactivity and reactor effluents. Traceability to NBS is achieved by testing of the

NRC Reference Laboratory and by provision of standard samples and test samples of radioactivity for use in the states and the nuclear power industry.

A similar program was started under sponsorship of the Environmental Protection Agency. Its purpose is to have NBS develop standard reference materials for radiological pollutants associated with energy sources and production, and to conduct traceability studies with the EPA Reference Laboratory.

Medical diagnostic, therapeutic

For almost 50 years, NBS has developed and maintained the primary physical measurement standards which serve as a common reference for measurements made during medical applications of ionizing radiation. These standards are disseminated through calibrations of secondary standards and through measurement assurance programs. Examples follow:

One project carried out in cooperation with BRH provides measurement assurance for cancer therapy with cobalt-60 radiation. Thermoluminescence dosimeters are mailed to users of teletherapy equipment, who irradiate them under prescribed conditions and return them to NBS for evaluation. NRC has responsibility for licensing the safe use of such radiation sources. To date , over one-half of the 1,000 units in the United States have been surveyed. As many of the remaining units as possible will be surveyed this year. It is planned to follow with a similar measurement-assurance survey of linear accelerator sources used for photon therapy, with continuing support from BRH.

A similar NBS service carried out for several years provides a common basis for all electron-beam cancer therapy in the U.S. by establishing traceability to national dosimetry standards. The objective of a related activity is to develop methods, techniques, and apparatus to reduce the radiation exposure to the general population from diagnostic x-ray examinations.

Other biological or physical effects studies

NBS maintains a small but effective program which is directed generally toward development of the basic data which describe the physical interaction of ionizing radiation with biological materials. This program does not attempt to study biological effects of radiation, but forms the measurement basis for effects studies done by others. Accurate, reliable data are essential for understanding the mechanisms by which radiation energy is absorbed in biological or equivalent materials.

Other studies

To disseminate the national measurement standards, NBS calibrates customers' instruments using the national standards as a reference. In addition, special tests are performed on measurement instruments provided by various sponsors. Radioactive sources are also calibrated for appropriate customers. These services are provided on a reimbursable cost basis.

DESCRIPTION OF NBS PROGRAM

LASER RADIATION

NOTE. (1) Funds in thousands of dollars. (2) Extra-mural funds are those obtained from other agencies to support NBS in-house programs. (3) Total funds include support from other agencies and support from the NBS appropriation.

The principal objectives of the program are to (1) develop laser power and energy physical measurement standards for key lasers impacted by the FDA laser performance standard, and (2) develop transfer standards, measurement methods, and a quality control program for laser power and energy measurements so that laser manufacturers can make valid measurements to help them comply with the FDA standard.

A laser power and energy measurement assurance program was established recently by NBS. In this program a calibrated transfer standard is sent to the participant so that he can perform intercomparisons at his site. The measurement analysis is provided by NBS. This measurement assurance program was established in cooperation with the Bureau of Radiological Health.

NONIONIZING RADIATION [1]—LASER

Year	Studies to determine human health effects	Ecological efforts, animal/plant	Agricultural effects, plant/animal	Criteria and/or standards development	State/Federal liaison	Licensing, certification, inspection	Monitoring and/or surveillance	Medical, diagnostic, therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain)	Other studies (explain)
1968:												
In-house (positions)												
Extramural (funds)												
Total funds												
1969:												
In-house (positions)												
Extramural (funds)												
Total funds												
1970:												
In-house (positions)												
Extramural (funds)												
Total funds												
1971:												
In-house (positions)												
Extramural (funds)												
Total funds												
1972:												
In-house (positions)				2								
Extramural (funds)				20								
Total funds				100								
1973:												
In-house (positions)				2								
Extramural (funds)				19								
Total funds				100								
1974:												
In-house (positions)				4								
Extramural (funds)				20								
Total funds				265								
1975:												
In-house (positions)				5								
Extramural (funds)				45								
Total funds				283								
1976:												
In-house (positions)				3								
Extramural (funds)				65								
Total funds				144								
1977:												
In-house (positions)				2								
Extramural (funds)				43								
Total funds				100								
1978 estimate:												
In-house (positions)				1								
Extramural (funds)				25								
Total funds				75								

---

[1] Identify type of nonionizing radiation, e.g., microwave, ultrasound, etc.

DESCRIPTION OF NBS PROGRAM

RF AND MICROWAVE RADIATION

NOTE. (1) Funds in thousands of dollars. (2) Extra-mural funds are those obtained from other agencies to support NBS in-house programs. (3) Total funds include support from other agencies and support from the NBS appropriation.

The entry in the column headed "Collection and/or analysis of environmental data" relates to measurements of RF and microwave radiation from communication systems, radars, and navigation systems at airports and on aircraft. This work is supported by the FAA and results are reported to that agency. Instrumentation for the surveys was developed by NBS.

The entry in the "Other Studies" column relates to efforts in measurement theory, techniques, and instrumentation which support measurements made for various purposes. For the most part, these efforts develop the measurement basis required to determine radiation hazards as defined by some other agency or organization. There has been fluctuating support for this program from other agencies, including BRH, EPA, OSHA/NIOSH, and the FAA. A project was recently initiated to develop measurement support for the study of various problems caused by electromagnetic interference.

NONIONIZING RADIATION[1]—RF AND MICROWAVE

Year	Studies to determine human health effects	Ecological efforts, animal/plant	Agricultural effects, plant/animal	Criteria and/or standards development	State/Federal liaison	Licensing, certification, inspection	Monitoring and/or surveillance	Medical, diagnostic, therapeutic	Collection and/or analysis of health data	Collection and/or analys's of environmental data	Other biological or physical effects studies (explain)	Other studies (explain)
1968:												
In-house (positions)												
Extramural (funds)												
Total funds												
1969:												
In-house (positions)												1
Extramural (funds)												50
Total funds												60
1970:												
In-house (positions)												1
Extramural (funds)												60
Total funds												70
1971:												
In-house (positions)												3
Extramural (funds)												120
Total funds												135
1972:												
In-house (positions)												3
Extramural (funds)												100
Total funds												150
1973:												
In-house (positions)												3
Extramural (funds)												100
Total funds												150
1974:												
In-house (positions)										1		3
Extramural (funds)										50		110
Total funds										50		150
1975:												
In-house (positions)										1		5
Extramural (funds)										20		215
Total funds										20		321
1976:												
In-house (positions)										2		3
Extramural (funds)										90		15
Total funds										90		180
1977:												
In-house (positions)										1		5
Extramural (funds)										30		160
Total funds										30		280
1978 estimate:												
In-house (positions)												6
Extramural (funds)												160
Total funds												320

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[1] Identify type of nonionizing radiation, e.g., microwave, ultrasound, etc.

DESCRIPTION OF NBS PROGRAM

ULTRASONIC RADIATION

NOTE. (1) Funds in thousands of dollars. (2) Extra-mural funds are those obtained from other agencies to support NBS in-house programs. (3) Total funds include support from other agencies and support from the NBS appropriation.

The attached column entry refers to NBS activities leading to physical measurement standards for characterizing ultrasonic transducers and to transfer standards for calibrating radiated ultrasonic power. Two calorimeters for the measurement of time-averaged total power output of ultrasonic transducers have been developed; one resides at BRH to provide them with a basic standard for regulatory action. (BRH provided the indicated other-agency support in 1974 and 1975.) Transfer ultrasonic transducers have been developed for use in evaluating radiated ultrasonic power measuring systems. An international intercomparison of power measurement is being based on this transfer mechanism. A scanning technique for determining field point intensity of radiated ultrasound is well along and will be used to provide a measurement service for the evaluation of medical transducers. It is believed that the point parameters are critical with respect to possible biological damage.

NONIONIZING RADIATION[1]—ULTRASOUND

Year	Studies to determine human health effects	Ecological efforts, animal/plant	Agricultural effects, plant/animal	Criteria and/or standards development	State/Federal liaison	Licensing, certification, inspection	Monitoring and/or surveillance	Medical, diagnostic, therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain)	Other studies (explain)
1968:												
In-house (positions)												
Extramural (funds)												
Total funds												
1969:												
In-house (positions)												
Extramural (funds)												
Total funds												
1970:												
In-house (positions)												
Extramural (funds)												
Total funds												
1971:												
In-house (positions)												
Extramural (funds)												
Total funds												
1972:												
In-house (positions)				2								
Extramural (funds)				0								
Total funds				100								
1973:												
In-house (positions)				2								
Extramural (funds)				0								
Total funds				100								
1974:												
In-house (positions)				3								
Extramural (funds)				50								
Total funds				200								
1975:												
In-house (positions)				3								
Extramural (funds)				50								
Total funds				200								
1976:												
In-house (positions)				2								
Extramural (funds)				0								
Total funds				14								
1977:												
In-house (positions)				2								
Extramural (funds)				0								
Total funds				110								
1978:												
In-house (positions)				2								
Extramural (funds)				20								
Total funds				140								

---

[1] Identify type of nonionizing radiation; e.g., microwave, ultrasound, etc.

DESCRIPTION OF NBS PROGRAM

ULTRAVIOLET RADIATION

NOTE. (1) Funds in thousands of dollars. (2) Extra-mural funds are those obtained from other agencies to support NBS in-house programs. (3) Total funds include support from other agencies and support from the NBS appropriation.

The NBS program has as its purpose the development of standards and measurement capabilities for UV radiation adequate to satisfy the requirements of modern technology and to provide a national measurement base necessary both for the development of laws and regulations and for ensuring their compliance in order to protect the public and the environment from possible adverse effects of such radiation. A large fraction of the recent work in this area is related to the development of measurement methods for studying the biological and climatological effects of changes in UV radiation reaching the earth from the sun and to the prevention of hazardous public exposure to UV in situations involving industrial UV processing, artificial illumination, and medical therapy.

NONIONIZING RADIATION [1]—ULTRAVIOLET

Year	Studies to determine human health effects	Ecological efforts, animal/plant	Agricultural effects, plant/animal	Criteria and/or standards development	State/Federal liaison	Licensing, certification, inspection	Monitoring and/or surveillance	Medical, diagnostic, therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmental data	Other biological or physical effects studies (explain)	Other studies (explain)
1968:												
In-house (positions)												2
Extramural (funds)												59
Total funds												83
1969:												
In-house (positions)												2
Extramural (funds)												62
Total funds												87
1970:												
In-house (positions)												2
Extramural (funds)												70
Total funds												98
1971:												
In-house (positions)												2
Extramural (funds)												74
Total funds												104
1972:												
In-house (positions)												4
Extramural (funds)												120
Total funds												215
1973:												
In-house (positions)												5
Extramural (funds)												126
Total funds												226
1974:												
In-house (positions)												5
Extramural (funds)												134
Total funds												240
1975:												
In-house (positions)												6
Extramural (funds)												181
Total funds												351
1976:												
In-house (positions)												8
Extramural (funds)												285
Total funds												522
1977:												
In-house (positions)												9
Extramural (funds)												398
Total funds												618
1978 estimate:												
In-house (positions)												9
Extramural funds)												340
Total funds												665

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[1] Identify type of nonionizing radiation, e.g., microwave, ultrasound, etc.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION,
Washington, D.C., June 9, 1977.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology, and Space Subcommittee; Committee on Commerce, Science, and Transportation.

Hon. WENDELL H. FORD,
Chairman, Consumer Subcommittee, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMEN: This is in further response to your letter of May 19, 1977, concerning the Committee's plans to hold hearings to review and evaluate Federal radiation research and regulatory programs.

Enclosed herewith is a report, with attachments, describing NASA's research activities in the radiation field. The format of this response, in lieu of using the matrices provided, has been discussed with Mr. Dan Jaffe of the Committee staff.

Should additional information or clarification be required, NASA will be pleased to work with the Committee staff.

Sincerely,

A. M. LOVELACE,
Acting Administrator.

Enclosure.

RADIATION RESEARCH ACTIVITIES OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

The NASA Life Sciences division directs a segment of its total research program to studies to determine human health effects of space radiation. These studies are organized under a single Research and Technology Operating Plan (RTOP) which is titled, "Radiation Effects and Protection." The goals of this research are outlined in Attachment 1, but it should be recognized that much of this information is reliant on the research of other agencies.

The NASA program has been considerably reduced over the years to its current $500–600K per year level. Consequently, NASA has narrowed its sponsorship of research projects to those areas which are unique to NASA interests and are not adequately covered elsewhere, either because of the problems themselves, particular aspects of the problems, or timing. NASA current research is, therefore, almost entirely limited to effects (A) and dosimetry (B) of high energy heavy particle (HZE) radiation (cosmic radiation from galactic and solar sources in space), and a smaller effort to extract further information on other forms of ionizing radiation from existing NASA flight and ground-based data sources. The HZE research is heavily dependent upon support of the Bevalac by the Energy Research and Development Administration. The Bevalac, a facility of the Donner Laboratory at the University of California at Berkeley, is the only ground-based HZE generator in the United States and, so far as is known, the only one in the world.

Items C, Medical Selection Factors, and D, Real Time Prognostication Techniques, are retained as goals for the future, but the present state of knowledge is such that work in these areas is not likely to be sufficiently productive for NASA purposes at this time. Consequently, NASA has no current activities in these areas.

With respect to Item E, Countermeasures, NASA is attempting to stimulate the physical sciences to give greater emphasis to shielding research, particularly to the development of mathematical transport equations for HZE ions as a means of exploring laminated materials or other new shielding techniques. NASA maintains an awareness of new developments in preventive agents, but does not conduct this research. Lastly, much of the NASA research will require space flight for confirmation and extension of the hypotheses generated. Item F, Preparation of Flight Experiments, is included to allow the early definition of such experiments as off-shoots of the ongoing ground-based research program prior to their full support from payload funds of a given flight program.

Attachment 2 is a task-by-task description of the current Radiation Effects and Protection RTOP (RTOP No. 199–45). Funding is indicated and prior years' programs are included as well.

The following is in specific reply to the four questions posed in the May 19, 1977, letter from Chairmen Stevenson and Ford:

Question. (1) What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. The jurisdictional changes which have taken place between 1968 and 1977 have not caused any major problem or affected NASA responsibilities or work in the radiation area.

Question. (2) Would you please describe the nature of the contacts between your organization and State groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with State agencies? Is there any confusion concerning respecitve responsibilities of State and Federal agencies?

Answer. NASA does maintain contact with some State agencies in the radiation field and on environmental matters. The contact is primarily of a cooperative and coordinational nature by NASA field Centers. With the exception of the National Space Technology Laboratories, which is licensed by the State of Mississippi, all NASA Centers come under the purview of Federal licensing procedures. All NASA contractors come under the purview of their respective State licensing and inspection regulations. NASA is not aware of any conflicts or confusion between State and Federal agencies either directly or through its grantees or contractors.

Question. (3) Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. Although there is some lack of uniformity which could be improved upon, the present regulations affecting NASA's radiation programs appear to be satisfactory. However, NASA believes the present funding levels are less than adequate. For example, shielding research has been reduced to a virtually non-functional level. Additional funding could be used in training technicians to deal with health hazards and to remedy the delays presently being encountered in amending licenses needed to conduct research projects.

Question. (4) What is your reaction to the proposals to consolidate all Federal radiation activities into one Federal radiation agency?

Answer. In NASA's view, the consolidation of all Federal radiation research activities into one agency would be a serious error. Radiation as a naturally occurring energy, of potential danger as well as utility, requires protective measures under varied circumstances and promises application to several kinds of problems. The interests and disciplines involved in these protective concerns and potential uses cannot be expected to be fully represented in one agency. For example, space radiation is unique. Ambient environments and protective requirements must be researched and fitted to the operational configuration of each flight mission. Similarly, the therapeutic application of different kinds of radiation to specific disease states must be explored under clinical conditions by the appropriate combinations of medical specialists. In both of these examples, the particular problems are properly those of the agencies involved, NASA and the Department of Health, Education, and Welfare/National Institutes of Health, respectively.

Fundamental studies of the energy, establishment of regulations for its use, regulatory authority, and certain applications, such as radiation as an energy source, could be housed in one central agency. Applied radiation problems, however, should continue to be explored by the agencies directly concerned with them.

ATTACHMENT 1—RESEARCH PROBLEMS

RTOP NO. 199-45: RADIATION EFFECTS AND PROTECTION

A. Determination of Acceptable Levels of Radiation Exposure (Responses of Living Systems and Mechanisms):
  (1) Dose—Response Relationships.
  (2) Mechanisms of Radiation Damage.
  (3) Methodology Development (for Evaluation).
B. Dosimetry of Space Environments for Living Systems:
  (1) Technique Development.
  (2) Improved Dose Expression (for Particle Radiation).
  (3) Dose Distribution Modeling.
C. Identification of Human Susceptibility Factors (Selection).
D. In-Flight (Real Time) Prognostication Techniques.
E. Countermeasures:
  (1) Preventive.
  (2) Protective.
F. Preparation of Flight Experiments.

ATTACHMENT 2

FISCAL YEAR 1977

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

F-41 NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL	
				TP	FY 77 (K)
-01-01	Benton/U. of San Francisco	Automated Analysis of HZE Particle Dosimeters (Bailey)	Development of an automated system for detecting HZE tracks in pack (Lexan-cellulose nitrate) dosimeters utilizing (and expanding) the analyzing microscope & developing control and analysis program for dedicated mini-computer, together with interface.	-	100
-01-02	TBD/In-House/JSC	Evaluation of Commercial Personal Dosimeters for Shuttle Application (Bailey)	Evaluation of commercially available (5 or more) active personal dosimeters for applicability (perhaps with small modification) to Shuttle requirements and specs. in effort to reduce costs (possible savings of $2-3 million).	-	15
-01-03	Pickering/USAF, Brooks	Radiation Effects of Manned Space Flight (Hoffman)	Investigation of pathological effects of HZE on monkey retinas & resultant changes in visual acuity; long-term effects of HZE to total body; effects of low dose/low dose rate gamma irradiation on monkeys; continuing study of proton irradiated monkeys for long-term effects.	-	80

FISCAL YEAR 1977

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL	
				TP	FY 77 (K)
-01-05	Tobias/U. of CA, Berkeley	Biomedical Significance of High Energy Multi-Charged Cosmic Rays (Hoffman)	Investigation of the biomedical effects of HZE particles on biological tissues, organ systems, and organisms (rat, rabbit, & mud puppy) using BEVALAC & evaluating function-histological, and molecular alterations; further study of light flash phenomenon; coordination with work at Colorado State (Lett) to determine RBE of HZE radiation.	-	100
-01-06	Lett/Colorado State	Effect of Cosmic Radiation on the Brain: Consequences of DNA Damage (Hoffman)	Investigation of HZE effects on non-dividing cells by studying DNA changes induced in neural cells of the retina & correlating functional, histological & molecular changes; rabbit retinas, excised or in situ, are exposed to various HZE beams & X-rays in this study; coordinated with Tobias (-06).	-	60
-01-10	Schaefer/NAMRL	Atlas of Nuclear Emulsion Micrographs (Bailey)	Preparation of an atlas of nuclear emulsion micrographs from the dosimeter packs of Gemini and Apollo, with a comprehensive evaluation of capabilities & limitations of nuclear emulsion dosimetry for calculation of LET distribution & RAD & REM doses for the various components of ionizing radiation in space; book almost completed-no further funds required.	10	-

FISCAL YEAR 1977

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

RTOP NUMBER: 199-45

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL	
				TP	FY 77 (K)
-01-12	In-House/JSC	Radiation Calibration Laboratory (Bailey)	Refurbishment of JSC radiation calibration facilities to support Shuttle; radiation sources (now decayed) to be replaced & equipment updated.	-	25
-01-13	McNulty/Clarkson College of Technology	Light Flash Phenomena Induced by HZE Particles	Investigation of the mechanisms by which HZE particles produce the "flashes of light" phenomenon observed by flight crews on Apollo and subsequent missions.	-	34.5
			JSC SUBTOTAL	10	414.5

FISCAL YEAR 1977

MEDICAL SCIENCES

AMES RESEARCH CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41 NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL	
				TP	FY 77 (K)
-02-01	Haymaker/U. of SF/ ARC	Effects of Heavy Particle Radiation on the Mammalian Brain & Related Tissues (Miquel)	Determination of effects of HZE on mammalian tissues, primarily the brain, by exposing pocket mice to known particles & intensities on the BEVALAC; near- & long-term effects (1 year) will be studied histologically, histochemically, and by electron microscopy; through dosimetry (by Benton) dose-response relationships at Bragg peak and shank will be established.	29	117
-02-02	In-House/ARC	Effects of Space Radiation on Nerve Tissue Cell (Miquel)	Comparison of biological damage resulting in drisophila and mouse brain single hits by nuclei of He, C, N, O & Ar in Lawrence Rad. Lab. cyclotron; determine if single hits will kill or inactivate nerve cells in vivo.	14	45
			ARC SUBTOTAL	43	162
			RTOP TOTALS	53	576.5

FISCAL YEAR 1976

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-01-01	Benton/U. of SF San Francisco	Automated Analysis of HZE Particle Dosimeters (Bailey)	Development of an automated system for detecting HZE tracks in pack (Lexan-cellulose nitrate) dosimeters utilizing (and expanding) the analyzing microscope & developing control and analysis program for dedicated mini-computer, together with interface.	75
-01-03	TBD/In-House/JSC	Evaluation of Commercial Personal Dosimeters for Shuttle Application (Bailey)	Evaluation of commercially available (5 or more) active personal dosimeters for applicability (perhaps with small modification) to Shuttle requirements and specs. in effort to reduce costs (possible savings of $2-3 million).	10
-01-04	Pickering/USAF, Brooks	Radiation Effects of Manned Space Flight (Hoffman)	Investigation of pathological effects of HZE on monkey retinas & resultant changes visual acuity; long-term effects of HZE to total body; effects of low dose/low dose rate gamma irradiation on monkeys; continuing study of proton irradiated monkeys for long-term effects.	95
-01-05 (TERMINATED)	Lushbaugh/Oak Ridge Assoc. U.	Human Radiosensitivity (Hoffman)	Long-term data gathering effort on human responses to radiation, especially to long duration-low dose rate exposure; data derived from low dose rate radiation therapy (mostly gamma) in recent years earlier data obtained from retrospective questionnaires & accident data); purpose to permit definition of acceptable exposure limits.	-

FISCAL YEAR 1976

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-01-06	Tobias/U. of CA, Berkeley	Biomedical Significance of High Energy Multi-Charged Cosmic Rays (Hoffman)	Investigation of the biomedical effects of HZE particles on biological tissues, organ systems, and organisms (rat, rabbit, & mud puppy) using BEVALAC & evaluating functional, histological, and molecular alterations; further study of light flash phenomenon; coordination with work at Colorado State (Lett) to determine RBE of HZE radiation	100
-01-07	Lett/Colorado State	Effect of Cosmic Radiation on Brain: Consequences of DNA Damage (Hoffman)	Investigation of HZE effects on non-dividing cells by studying DNA changes induced in neural cells of the retina & correlating functional, histological & molecular changes; rabbit retinas, excised or in situ, are exposed to various HZE beams & X-rays in this study; coordinated with Tobias (-06).	10
-01-08	Schaefer/NAMRL	Energy Dissipation Characteristics of HZE Particles (Bailey)	Continuation of analyses and calculations necessary to characterize the HZE environment in space in a format utilizable by the health physicist & radiobiologist by refining flight & flight crew dosimetry data on HZE distribution by atomic number & energy; will soon complete the theoretical analysis of all current data on the galactic radiation environment & focus on radiation problems of orbital flight.	15

FISCAL YEAR 1976

MEDICAL SCIENCES

JOHNSON SPACE CENTER

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

RTOP NUMBER: 199-45

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-01-12 (TERMINATED)	Schaefer/NAMRL	Atlas of Nuclear Emulsion Micrographs (Bailey)	Preparation of an atlas of nuclear emulsion micrographs from the dosimeter packs of Gemini & Apollo, with a comprehensive evaluation of capabilities & limitations of nuclear emulsion dosimetry for calculation of LET distribution & RAD & REM doses for the various components of ionizing radiation in space; book almost completed-no further funds required.	0
			JSC SUBTOTAL	355

FISCAL YEAR 1976

MEDICAL SCIENCES

AMES RESEARCH CENTER

RADIATION EFFECTS & PROTECTION

RTOP NUMBER: 199-45

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL (K)
-02-13	Haymaker/U. of SF/ ARC	Effects of Heavy Particle Radiation on the Mammalian Brain & Related Tissues (Miquel)	Determination of effects of HZE on mammalian tissues, primarily the brain, by exposing pocket mice to known particles & intensities on the BEVALAC; near- & long-term effects (1 year) will be studied histologically, histochemically, and by electron microscopy; through dosimetry (by Benton) dose-response relationships at Bragg peak and shank will be established.	90
-02-14	In-House/ARC	Effects of Space Radiation on Nerve Tissue Cell (Miquel)	Comparison of biological damage resulting in drisophila and mouse brain from single hits by nuclei of He, C, N, O, & Ar in Lawrence Rad. Lab. cyclotron; determine if single hits will kill or inactivate nerve cells in vivo.	45
-02-15	In-House/ARC	Particle Track Location & Radiation Induced Effects in Cells & Tissues (Philpott)	Development of new techniques to simplify HZE dosimetry & tissue damage identification by evaluating use of tissue dyes (which will couple with blood proteins), tracers (i.e., ferratin) which will not enter cells, and radiosensitive plastic dyes (for dosimetry); studies will use small rodents and analyze (EM) HZE hits in vascular tissues after dye marker injection I.V; also Kosmos mice will be evaluaby P.I. in this task.	20

FISCAL YEAR 1976

MEDICAL SCIENCES

AMES RESEARCH CENTER

RTOP NUMBER: 199-45

RADIATION EFFECTS & PROTECTION

Agency Coordinator J.V.Bailey, Ph.D.
Other Center Contact J.L.Sharp, Ph.D.

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-02-16 (TERMI-NATED)	Tobias/Lawrence Rad. Laboratory	Radiation and Gravitational Biology in Relation to Space Flight	Determination of biological effects of HZE & the possible synergistic effects of OG & ionizing radiation; continuation of post-biosatellite studies of Tribolium, tissue cultures, seeds, etc.; development of new HZE experimentsfor flight; participate in ASTP biostack consortium in FY 76.	-
-02-17	Benton/U. of SF/ARC	HZE Particle Dosimetry and Tracking Study (Taketa)	Application (and further development) of plastic dosimetric technique for HZE to laboratory and flight studies in support of the work of several P.I.'s; evaluate & correlate determinations of trajectory, flux, energy, charge, & residual range of particles and effects on biologic targets; upgrade methods of counting, processing, and data handling.	45
			ARC SUBTOTAL	200
			RTOP TOTALS	555

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

AMES RESEARCH CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-21-63

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-01	C. Tobias/U. of CA	Radiation & Gravitational Biology in Relation to Space Flight (S. Taketa) W12-792 (06)	Establish and understand biologic effects of HZE particles & of combined radiation & various gravitational states by exposing biologic material (seeds, Tribolium, mammals, etc.) to accelerator-produced heavy ions (N,O, etc.) and/or various gravitational states & finally space flight experiments to correlate with ground-based data.	120
-05	W. Haymaker/U. of SF	HZE Particle Irradiation of Mammals	Mammals, including pocket mouse, will be exposed to HZE particle irradiation using BEVALAC. Dose-response curves will be established. Results will be compared with BIOCORE. Tolerance curves for human exposure will be constructed by extrapolation from animal results.	70
-06	J. Miquel/In-House	Effects of Space Radiation on Nerve Tissue Cells (N/A)	Determine if single hits by HZE from cyclotron sources will inactivate nerve cells by exposing drosophila to various kinds of particles (nuclei of H, C, N, O, and argon) and studying changes in DNA, endoplasmic reticulum & investigate tissue response.	45

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

AMES RESEARCH CENTER

RTOP NUMBER: 970-21-63

RADIATION BIOLOGY

Agency Coordinator________
Other Center Contact________

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-07	S. Taketa & E. Benton In-House & U. of SF	HI-LET Dosimetry & Tracking (Taketa) NAS 2-7059	Develop nuclear track detectors that measure rate of production & energy spectra of high-LET recoil particles induced in tissue equivalent material by heavy ions. Identify trajectory flux, charge & energy of incident particles on biologic targets.	35
-11	D. Philpott/In-House	Particle Track Location & Radiation Induced Effects in Cells and Tissues	Conduct studies to find a simple and effective method for locating radiation tracks in damaged cells by using dyes, tracer substances & laser light.	20
-17	Syverton/In-House	Neutron Energy Spectra & Dose Rates at Aircraft Altitudes	Data will aid in resolving controversies reported in the literature concerning the shape of the spectra and the relative contribution of fast neutrons to the total neutron dose. The validity of existing computer codes for calculating neutron fluxes will be tested. Variations in the spectra with time at a given reference point in the atmosphere during a significant portion of the solar cycle will be determined. Changes in the spectra as a	-

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

AMES RESEARCH CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-21-63

T-41 NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-17 (cont.)			function of altitude and latitude will be reassessed. The total radiation dose and the percentage of the dose contributed by neutrons will be measured. A capability for determining the effect of a solar flare on the neutron flux and radiation dose at aircraft altitudes will be developed.	
			ARC SUBTOTAL	290

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RTOP NUMBER: 970-51-63

RADIATION BIOLOGY

Agency Coordinator____________
Other Center Contact____________

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-03	J. Pickering/SAM	Radiation Effects in Manned Space Flight (Hoffman) T-64131	Study the effects of radiation on monkeys (monkey retina, visual acuity and the whole animal) by exposing the animal to HZE particles, protons, and low dose/dose rate gamma radiation (all separately). Emphasis on subtle changes from chronic irradiation.	100
-04	C. Lushbaugh/Oak Ridge Associated University	Human Radiosensitivity (Hoffman) T-88566	Document human responses to low doses of accumulated radiation and to radiation in general using data from past accidental radiation exposures, whole body radiation therapy cases, clinical observations and laboratory measurements.	65
-05	C. Tobias/U. of CA/ Berkeley	Biomedical Significance of High Energy Multi-Charged Cosmic Rays (Hoffman) T-7163B	Investigate the biomedical effects of HZE particles on biologic tissue, organ systems and organisms by conducting (1) studies using reports of investigations of visual sensations induced in humans by HZE particles and (2) molecular and cellular studies employing the BEVALAC to provide the HZE exposure.	100

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-51-63

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-08	J. Lett/Colorado St. University	Effect of Cosmic Radiation on Brain- Consequences of DNA Damage (Hoffman) NGR 06-002-128	Determine the effects of highly ionizing radiation on the function of non-dividing cells and molecules by irradiating rabbit retinas and correlating function, histologic damage, and molecular changes (DNA fragmentation). This effort investigating DNA effects of HZE irradiation complements cellular and organ studies in Tasks -05 and -08.	75
-09	H. Schaefer/NAMRL	Dissipation of HZE Particles (Hoffman) W-13280	Continue analysis of the physical measurements made as part of the crew dosimetry program during manned space flight to establish the best possible Z and E spectra and compare these findings with that of other investigators to characterize the HZE particle environment in space.	15
-10	H. Aceto/William & Mary	Space Related Mammalian Radiobiological Studies (Hoffman) NGR 47-006-054	Evaluate selected organ responses to low dose radiation and compare these responses to that of the whole organism by exposing rats to different dose levels and dose profiles of various types of ionizing radiation.	70

FISCAL YEAR 1975

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-51-63

T-14 NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-12	M. Billings/MDAC	Computerized Anatomical Man Model (Bailey) NAS 9-13228	Complete computerized anatomic man model (CAM); verify the accuracy and usability of the CAM concept, and apply CAM to design of dosimetry systems for Shuttle to evaluate, monitor and project the risk of space radiation.	-
-13	H. Scaefer/NAMRL	Atlas of Nuclear Emulsion Micrographs (Bailey) T-3057C	Develop a comprehensive pictorial record of the space radiation environment on various types of manned space flight missions by conducting a systematic microphotographic exploitation of nuclear emulsion dosimetry from Gemini & Apollo missions.	-
			JSC SUBTOTAL	425
			RTOP TOTALS	715

FISCAL YEAR 1974

BIOMEDICAL RESEARCH DIVISION

AMES RESEARCH CENTER

RTOP NUMBER: 970-21-63

RADIATION BIOLOGY

Agency Coordinator ________
Other Center Contact ________

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL (K)
-01	C. Tobias/U. of CA	Radiation & Gravitational Biology in Relation to Space Flight (S. Taketa) W12-792 (06)	Establish and understand biologic effects of HZE particles & of combined radiation & various gravitational states by exposing biologic material (seeds, Tribolium, mammals, etc=) to accelerator-produced heavy ions (N, O, etc.) and/or various gravitational states & finally space flight experiments to correlate with ground-based data.	125
-05	W. Haymaker/In-House	Effects of Solar & Galactic Particles on the Brain (N/A)	Study the effects of solar particles & HZE particles on brain, eyes, & other organs of monkeys, mammals and insects and of the pocket mice flown in Apollo 17.	70
-06	J. Miquel/In-House	Effects of Space Radiation on Nerve Tissue Cells (N/A)	Determine some effects & develop capability for early detection of radiation on nervous tissue by exposing drosophila to doses of 40A and study changes in DNA, endoplasmic reticulum & virus accumulations. Expose rats & pocket mice brains to particle radiation & investigate tissue response.	40
-07	S. Taketa & E. Benton In-House & U. of SF	HI-LET Dosimetry & Tracking (Taketa) NAS 2-7059	Develop nuclear track detectors that measure rate of production & energy spectra of high-LET recoil particles induced in tissue equivalent material by heavy ions. Identify trajectory flux, charge & energy of incident particles on biologic targets.	25

FISCAL YEAR 1974

BIOMEDICAL RESEARCH DIVISION

AMES RESEARCH CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-21-63

T-41 NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-11	D. Philpott/In-House	Particle Track Location & Damage in Cell Tissues (N/A)	Conduct studies to find a simple and effective method for locating radiation tracks in damaged cells by using dyes, tracer substances & laser light.	20
-14	W. Haymaker/In-House	Effect of Galactic Particles on Brains of Pocket Mice (N/A)	Complete microscopic study of brain & other tissues in comparison to control mice & ascertain whether heavy cosmic particles produced lesions in the brains and eyes of the 5 pocket mice carried on Apollo 17 flight.	20
			ARC SUBTOTAL	300

FISCAL YEAR 1974

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RADIATION BIOLOGY

Agency Coordinator______________
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RTOP NUMBER: 970-51-63

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-03	J. Pickering/SAM	Radiation Effects on Manned Space Flight (Hoffman) T-64131	Study the effects of radiation on monkeys (monkey retina, visual acuity and the whole animal) by exposing the animal to HZE particles, low dose/dose rate radiation (all separately).	100
-04	C. Lushbaugh/Oak Ridge Associated University	Human Radiosensitivity (Hoffman) T-88566	Document human responses to low doses of accumulated radiation and to radiation in general using data from past accidental radiation exposures, whole body radiation therapy cases, clinical observations and laboratory measurements.	120
-05	C. Tobias/U. of CA/ Berkeley	Biomedical Significance of High Energy Multi-Charged Cosmic Rays (Hoffman) T-7163B	Investigate the biomedical effects of HZE particles on biologic tissue, organ systems and organisms by conducting (1) studies using reports of investigations of visual sensations induced in humans by HZE particles and (2) molecular and cellular studies.	100
-06	D. Hightower/TX A&M	Radiation Effects Control - Skin & Eyes (Hoffman) NAS 9-9053	Define the effects of proton radiation on the skin & eyes by irradiating rabbits and dogs with low energy protons from a variable energy cyclotron.	40

FISCAL YEAR 1974

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RADIATION BIOLOGY

RTOP NUMBER: 970-51-63

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T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-08	J. Lett/Colorado St. University	Effect of Cosmic Radiation on Brain - Consequences of DNA Damage (Hoffman) NGR 06-002-128	Determine the effects of highly ionizing radiation on the function of non-dividing cells and molecules by irradiating rabbit retinas and correlating function, histologic damage, and molecular changes (DNA fragmentation).	65
-09	H. Schaefer/NAMRL	Dissipation of HZE Particles (Hoffman) W-13280	Continue analysis of the physical measurements made as part of the crew dosimetry program during manned space flight to establish the best possible Z and E spectra and compare these findings with that of other investigators.	15
-10	H. Aceto/William & Mary	Space Related Mammalian Radiobiological Studies (Hoffman) NGR 47-006-054	Evaluate selected organ responses to ionizing radiation and compare these responses to that of the whole organism by exposing rats to different dose levels and dose profiles of various types of ionizing radiation.	90
-12	M. Billings/MDAC	Computerized Anatomical Man Model (Bailey) NAS 9-13228	Complete computerized anatomic man model (CAM); verify the accuracy and usability of the CAM concept, and apply CAM to design of dosimetry systems for Shuttle to evaluate, monitor and project the risk of space radiation.	40

FISCAL YEAR 1974

BIOMEDICAL RESEARCH DIVISION

JOHNSON SPACE CENTER

RADIATION BIOLOGY

Agency Coordinator__________
Other Center Contact__________

RTOP NUMBER: 970-51-63

T-41

NUMBER	PI/INSTITUTION	TASK TITLE/TECHNICAL MONITOR	SUMMARY	FUNDING LEVEL
				(K)
-13	H. Schaefer/NAMRL	Atlas of Nuclear Emulsion Micrographs (Bailey) TBD	Develop a comprehensive pictorial record of the space radiation environment on various types of manned space flight missions by conducting a systematic microphotographic exploitation of nuclear emulsion dosimetry from Gemini & Apollo missions.	50
			JSC SUBTOTAL	620
			RTOP TOTALS	920

National Science Foundation,
Washington, D.C., June 23, 1977.

Hon. Adlai E. Stevenson,
Chairman, Subcommittee on Science, Technology and Space, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

Dear Senator Stevenson: This is in reply to your letter of May 19 from Senator Ford and you to Dr. Atkinson, the NSF Director, concerning background for the June hearings on Federal radiation research and regulatory programs.

We are sorry that there has been the delay in your receiving the Foundation's answer. The delay was due, in part, to the fact that the letter was referred to a number of NSF programs in an attempt to make sure all relevant programs were queried.

This letter will confirm the telephone report I gave on June 21 to Ms. Sharon Nelson of your staff that the Foundation is not supporting research in the area of radiation health and safety research and regulation. We are, however, providing substantial support for facilities that produce radiation for research through the Division of Physics (nuclear and elementary particle accelerators) and the Division of Materials Research (synchrotron facilities). The facilities operated by NSF grantees that produce radiation are subject to monitoring for safety, but the Foundation does not get directly involved in these monitoring activities. Such monitoring is the responsibility of the grantee institution and is subject to all Federal, State, and local regulations.

We look forward to reading the statements and discussion from the set of hearings currently under way, and appreciate your informing the Foundation of your plans to hold the hearings.

Sincerely yours,

Patricia E. Nicely,
Head, Congressional Liaison Branch.

Federal Communications Commission,
Washington, D.C., June 13, 1977.

Hon. Adlai E. Stevenson,
Hon. Wendell H. Ford,
Committee on Commerce, Science, and Transportation,
Washington, D.C.

Dear Senators Stevenson and Ford: The Commission's program since 1968 in the radiation area has been primarily attending meetings held by ERMAC and other groups concerned with the problems of radiation. We have expended approximately one half a man year for each of the years from 1968 to 1975. The exception to this was a project originated in 1972 where the Office of Chief Engineer and Field Operations Bureau of the FCC initiated program XZ17. (See attachment). The man years expended on this program was approximately one. In 1976 we expended one man year. In addition to attending meetings, time was spent gathering current information on radiation hazards. In 1977 and 1978 we expect to expend between 3 to 4 man years due to the increase in correspondence and in forming any additional rules or regulations that may be required as a result of present research projects.

In response to your first question, the only change in FCC responsibility was the enactment of P.L. 90–602. The Commission in Docket 19555 Appendix 3 addressed the OSHA standard 29 CFR 1910.95.

The only contact that FCC has had with state groups was a request in 1975 from the Texas State Department of Health requesting comments on a draft of Texas Regulations for the Control of Radio Frequency Electromagnetic Radiation. The FCC did not furnish any comments. We are not aware of any confusion concerning respective responsibilities of the states and FCC.

As for present regulations, we hope that the research projects presently being carried out by HEW and other government agencies will result in a more meaningful standard than the present 10 mw/cm^2 for all frequencies from 10 MHz to 100 GHz.

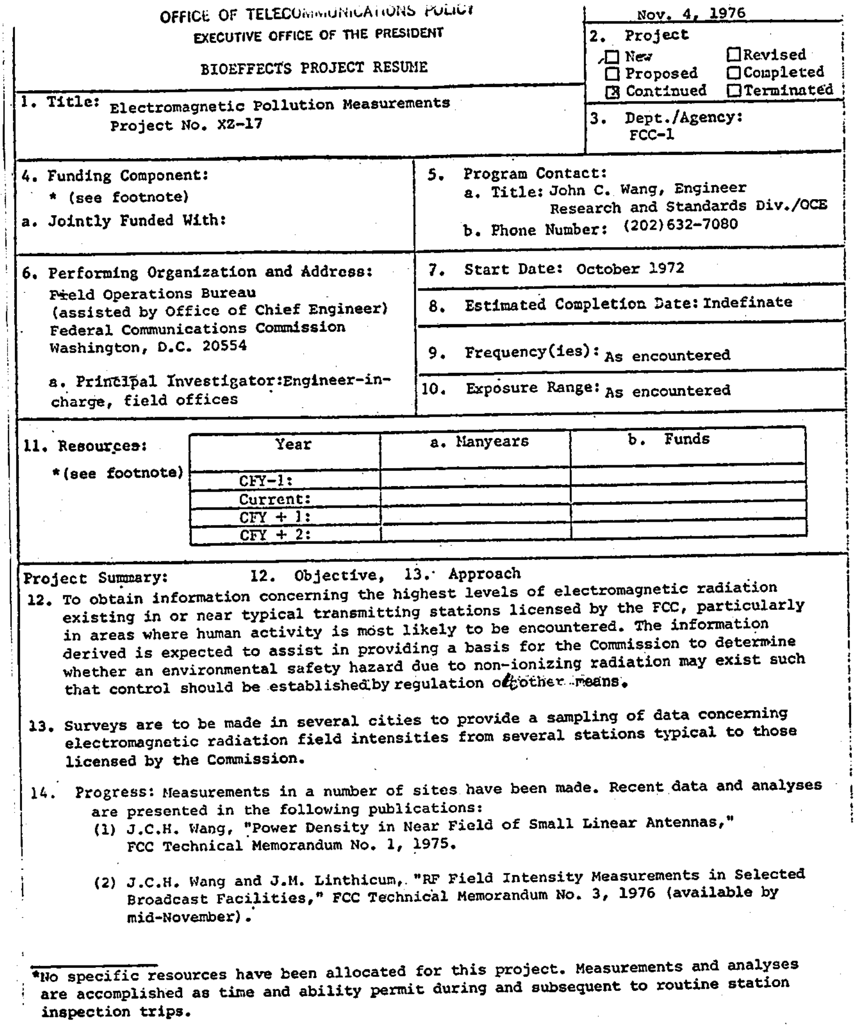
The FCC does not have the expertise or resources to be able to set radiation standards relative to biological effects. However, we are concerned that radio frequency equipment operating within the limits we set to reduce radio interference may still be harmful to persons nearby. We have exchanged correspondence with several bureaus and offices within both HEW and EPA relative to possible problems should the Commission allocate additional frequencies for use in a CB-type service in the vicinity of 27 MHz, 220 MHz or 900 MHz. Those responding to our inquiries all pointed to the ANSI C95.1–1974 standard, but some feeling was apparent that this standard should be re-evaluated in light of new evidence. Additional information in the letters was occasionally confusing and/or contradictory. For example, the response from the National Institute for Occupational Safety and Health quotes a report stating that maximum power is absorbed by the human body near 27 MHz. However, a letter received from the National Institute of Environmental Health Sciences (also of HEW) states that at 27 MHz the wavelength is so long that very little energy is absorbed by the human body. There appears to be insufficient unity of thought and effort among present entities.

If I can be of further help, please do not hesitate to call on me or any member of the Commission's staff.

Sincerely,

RICHARD E. WILEY, *Chairman.*

Attachment.



OFFICE OF TELECOMMUNICATIONS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT

BIOEFFECTS PROJECT RESUME

Nov. 4, 1976

2. Project
☐ New ☐ Revised
☐ Proposed ☐ Completed
☒ Continued ☐ Terminated

1. Title: Electromagnetic Pollution Measurements
Project No. XZ-17

3. Dept./Agency:
FCC-1

4. Funding Component:
* (see footnote)
a. Jointly Funded With:

5. Program Contact:
a. Title: John C. Wang, Engineer
Research and Standards Div./OCE
b. Phone Number: (202)632-7080

6. Performing Organization and Address:
Field Operations Bureau
(assisted by Office of Chief Engineer)
Federal Communications Commission
Washington, D.C. 20554

a. Principal Investigator: Engineer-in-charge, field offices

7. Start Date: October 1972

8. Estimated Completion Date: Indefinate

9. Frequency(ies): As encountered

10. Exposure Range: As encountered

11. Resources:
*(see footnote)

Year	a. Manyears	b. Funds
CFY-1:		
Current:		
CFY + 1:		
CFY + 2:		

Project Summary: 12. Objective, 13. Approach

12. To obtain information concerning the highest levels of electromagnetic radiation existing in or near typical transmitting stations licensed by the FCC, particularly in areas where human activity is most likely to be encountered. The information derived is expected to assist in providing a basis for the Commission to determine whether an environmental safety hazard due to non-ionizing radiation may exist such that control should be established by regulation or other means.

13. Surveys are to be made in several cities to provide a sampling of data concerning electromagnetic radiation field intensities from several stations typical to those licensed by the Commission.

14. Progress: Measurements in a number of sites have been made. Recent data and analyses are presented in the following publications:
(1) J.C.H. Wang, "Power Density in Near Field of Small Linear Antennas," FCC Technical Memorandum No. 1, 1975.

(2) J.C.H. Wang and J.M. Linthicum, "RF Field Intensity Measurements in Selected Broadcast Facilities," FCC Technical Memorandum No. 3, 1976 (available by mid-November).

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*No specific resources have been allocated for this project. Measurements and analyses are accomplished as time and ability permit during and subsequent to routine station inspection trips.

Department of Agriculture,
Office of the Secretary,
Washington, D.C., June 17, 1977.

Hon. Wendell H. Ford,
U.S. Senate.

Dear Senator Ford: The following information is furnished as requested by your letter of May 19, 1977. A similar reply is also being sent to Senator Adlai E. Stevenson.

The U.S. Department of Agriculture (USDA) does not engage in any radiation health and safety research and regulation programs from which performance standards are developed to control the emission of electronic product radiation. USDA employees, who have been authorized by the Departmnet's Radiological Safety Committee (USDA/RSC), use radioactive materials and radiation emanating equipment as laboratory tools for agricultural research and development programs and as sources of radiation for sterilizing microorganisms and insects for disease or pest control programs.

The programs are conducted in accordance with terms and conditions of licenses granted to the Department by the U.S. Nuclear Regulatory Commission (USNRC) under the Atomic Energy Act of 1954, as amended. Thus, statements and answers to the four questions relate primarily to the Department's use of *ionizing radiation* in the form of radioactive materials and radiation emanating equipment pursuant to regulations imposed by the USNRC. They do not relate to non-ionizing radiation emanating products, nuclear power reactors, fuel cycle facilities, nuclear medicine, and radiation therapy. Those naturally occurring or cyclotron produced radioactive materials not regulated by the USNRC, but used by USDA employees, are controlled by the RSC in the same manner as USNRC regulated radioactive materials.

Answers to the four questions are as follows:

1. By Public Law 93–438 and Executive Order 11834, effective January 19, 1975, the U.S. Atomic Energy Commission (USAEC) was reorganized into two agencies—the U.S. Nuclear Regulatory Commission and the U.S. Energy and Research Development Administration. The change did not affect the Department's overall efforts in the radiation area significantly as the Department continues to operate under the licensing provisions administered by the Division of Materials and Fuel Cycle Facility Licensing. USNRC. Prior to the reorganization, this Division was called the Division of Materials Licensing and was a component of the USAEC.

Before the Radiation Control for Health and Safety Act of 1968 was enacted, the USDA/RSC decided to include x-ray machines and electron microscopes among the ionizing radiation emanating equipment for which it is responsible. Appropriate acquisition procedures and radiation safety requrements were developed and implemented. Thus, the enactment of the Act reinforced the RSC's decision and facilitated the administration of its procedures and safety requirements.

2. As a Federal agency using radioactive materials and/or radiation emanating equipment, the Department is subject only to the rules, regulations, and licensing requirements, promulgated by the USNRC and is exempt from state requirements. Occasionally, a state may request a report of radioactive materials that USDA personnel are using in facilities within its borders. Such information has been furnished as a cooperative courtesy rather than a regulatory requirement. Also, occasionally confusion arises as to whether a State or Federal agency has licensing jurisdiction and related safety responsibilities. Such confusion is usually due to lack of knowledge or availability of applicable regulations and procedures and can be clarified by contacting the Radiological Safety Staff.

3. Generally speaking, the regulation of the possession and use of radioactive materials and certain radiation emanating equipment has been satisfactory. Regulations could be improved by writing them in less legalistic language so that their interpretation and application would be simplified. The time interval from the time the applicant files an application for license or license amendment to the time he receives the license or amendment is too long. The procedures for amending regulations could be improved and expedited. Since we do not know what present funding levels are, we have no comments on this matter.

4. Department procedures for implementing current radiation health and safety regulations established by USNRC involves a small staff administered by the Agricultural Research Service to monitor and maintain surveillance of all USDA programs using sources of ionizing radiation. The procedure has been administratively efficient in that all scientists in the Department involved in radiation programs can obtain guidance from one source. We recommend retention of our Radiological Safety Staff and continuation of current USDA procedures.

Several advantages for a single Federal Radiation Regulatory Agency are apparent however: all regulatory expertise would be assembled in one agency to coordinate their efforts which could result in better regulations; though many different regulations and standards have to be developed for the many different types of potentially hazardous materials, it would appear that the regulations and standards would be more uniform and consistent; more efficient cooperation with other Federal, State, and private representatives having a related interest in the development of standards and regulations; any research testing, etc., in-house or by outside public or private organizations could be more efficiently negotiated and administered.

We have confined our input to the two matrices in the programs to Agricultural Effects (Research) Plant/Animal and to Monitoring and Surveillance.

Additional information is attached to the charts. A computer printout from the Program and Resource Information System is attached to provide examples of the type of research programs being conducted in USDA.

Sincerely,

JAMES NIELSON,
(For M. Rupert Cutler,
Assistant Secretary for Conservation, Research and Education).

Enclosures.

1. Information for 1968, 1972, and 1976 was retrieved from the Cooperative States Research Service's Current Research Information System. The research data stored in the system could not be retrieved by radiation type, therefore, entries in Chart I include both types of radiation research conducted by the Forestry Service, Agricultural Research Service, and by State Agricultural Experiment Stations with Federal funds administered by the Cooperative States Research Service.

2. Information for 1976 on Chart II was retrieved from the Agricultural Research Service, Program and Resource Information System (copy attached). It does not include the research programs conducted by the Forestry Service and the Cooperative States Research Service.

A review of each project with program coordinators and research scientists provided information for identifying the type of radiation involved.

IONIZING RADIATION

Chart I

Year	Research			Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural ~~Effects~~ Plant/Animl									
1968 In-House (Positions)			16.6 SY 17,000 787,000				4 NA 48,800					
1969 Extra-Mural (Funds) Total Funds							4 NA 53,800					
1970							4 NA 62,000					
1971							4 NA 67,200					
1972			24.7 SY None 1,374,000				4 NA 71,800					
1973							4 NA 77,800					
1974							5 NA 87,900					
1975							5 NA 94,600					
1976			15.8 SY 56,400 1,409,000				6 NA 100,800					
1977			11.2 SY 22,900 1,119,900				6 NA 112,600					
Est. 1978							6 NA 112,600					

applies to all years

NON-IONIZING RADIATION*

Chart II

*(identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Research											
	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Anim	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968												
1969												
1970												
1971												
1972												
1973												
1974												
1975												
1976			5.8 SY 49,600 539,200									
1977			5.2 SY None 516,900									
Est. 1978												

- In-House (Positions)
- Extra-Mural (Funds)
- Total Funds

applies to all years

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   6/06/77                               (CC)  CLASSIFICATION DATA, FUNDS AND SY AS OF  00000                              PAGE   1
                              ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                                                LAST YR               THIS YR
                       DETAIL LINES                                ACTI COMM SCIE TOT % RPA RP     ACTUAL $      SY     PLANNED $      SY

NI 1090-20611-001      FORT COLLINS          CO                    5900 2900 0710   10  503 603       1,157
   USE OF MICROWAVES TO EFFECT FEATHER RELEASE                     5900 2900 1920   25  503 603       2,892
                                                                   5900 2900 1924   40  503 603       4,627
   MILLER  B F         GOBLE  J W                         76/01/15 5900 2900 1925   10  503 603       1,157
   0042928                                                77/12/31 5900 2900 2630   15  503 603       1,735
                                                                                            SUM      11,567.

I  1090-20781-002      ITHACA                NY                    4300 0100 0912   20  102 101       6,940
   MEASUREMENT OF AVAILABILITY OF MAGNESIUM FROM HUMA              4900 6700 0912   20  318 701       6,940
   N FOODS USING STABLE 26MG AND RADIOACTIVE 28MG                  4900 6800 0910   10  318 701       3,470
   SCHWARTZ  RUTH      GRUNES  D L                        76/06/18 4900 3800 0913   20  318 501       6,940
   0043206                                                79/09/30 6300 4000 0912   10  708 501       3,470
                                                                   6300 4000 0913   20  708 501       6,940
                                                                                            SUM      34,701

   1090-20831-003      NEW YORK              NY                    4880 2600 0212   50  709 311                            11,465
I  MICRODISTRIBUTION OF PO-210 IN THE LUNGS OF RODENT              4880 2600 0213   50  709 311                            11,465
   S EXPOSED TO PO-210 AND PB-210                                                           SUM                           22,930.
   HARLEY  N           TSO  T C                           77/01/11
   0043604                                                78/01/31

   1090-20911-005      CINCINNATI            OH                    6300 4000 0913  100  708 501      38,055
   DIET AND NON-INVASIVE MEASUREMENT OF ATHEROSCLEROS                                       SUM      38,055.
NI IS IN MAN BY ULTRASONIC PULSE-ECHO IMAGING
   OLINGER  C          JUDD J                             76/03/12
   0043000                                                79/03/15

   1103-20791-001      AEQI, BELTSVILLE, MD                        4830 0100 0112   50  901 104      79,483    1.08        73,802    1.07
   CHEMISTRY AND MOVEMENT OF RADIONUCLIDES AND HEAVY               4890 0100 1528   50  901 104      79,483    1.08        73,802    1.07
I  METALS IN SOILS AND THEIR UPTAKE AND TRANSLOCATION                                       SUM     158,966.   2.15       147,603.   2.14
   LAGERWERFF  J V     TIFFIN  L O                        72/07/17
   0022896                                                77/07/17

I  1106-20392-005      APGI, BELTSVILLE, MD                        5000 2900 1310   70  310 403      20,552     .13        26,460     .22
   RADIOIMMUNOASSAY KITS FOR TURKEY GONADOTROPHINS                 5000 2900 0110   30  310 403       8,808     .05        11,340     .10
                                                                                            SUM      29,360.    .18        37,800.    .32
   WENTWORTH  B C      OPEL  H                            74/10/21
   0041824                                                77/10/21

I  1108-20100-002      PGGI, BELTSVILLE, MD                        5000 2000 0512   60  307 309      45,509     .52        71,000     .60
   FORAGE GRASS GENETICS, BREEDING, AND CYTOLOGY                   4500 2000 0512   10  207 309       7,585     .09        11,833     .10
                                                                   4600 2000 0512   10  208 309       7,585     .09        11,833     .10
   POWELL  J B                                            76/01/16 5100 2000 0512   20  405 309      15,170     .17        23,667     .20
   0042927                                                81/01/16                          SUM      75,848     .87       118,334    1.00

I  1108-20101-002      PGGI, BELTSVILLE, MD                        4900 1300 0212   25  906 315      12,050     .11        18,550     .16
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    6/06/77                               (CC)  CLASSIFICATION DATA, FUNDS AND SY AS OF  00000                         PAGE    2
                                  ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                                          LAST YR               THIS YR
                        DETAIL LINES                       ACTI COMM SCIE TOT % RPA RP    ACTUAL $      SY      PLANNED $     SY

    GENETICS AND BREEDING OF GRASSES FOR TURF              4900 1300 0512   25  906 315     12,050      .11       18,550     .16
                                                           5000 1300 0212   25  906 315     12,050      .11       18,550     .16
    POWELL  J B                                  74/02/14  5000 1300 0512   25  906 315     12,050      .11       18,550     .16
    0040815                                      79/02/14                           SUM     48,198      .45       74,200     .65

    1109-20172-004      PPHI, BELTSVILLE, MD               4900 6700 1312   50  318 701     57,053      .32       22,900     .18
NI  THE EFFECT OF ULTRA VIOLET RADIATION IN THE 280-32     4900 6700 0212   50  318 701     57,053      .32       22,900     .18
    0 NM RANGE ON PLANT PROCESSES                                                   SUM    114,106.     .63       45,800     .35
    KRIZEK  D T          CARNS  H R              75/10/31
    0040617              CHRISTIANSEN  M N       80/10/31

    1109-20193-001      PPHI, BELTSVILLE, MD               4900 6500 1920  100  318 701     27,054      .29       12,046     .13
VI  LIGHT AND RADIATION EQUIPMENT FOR INSECT CONTROL A                              SUM     27,054      .29       12,046     .13
    ND SURVEY
    CAMPBELL  L E                                70/04/07
    0017371                                      79/02/14

    3090-20041-005      WASHINGTON         DC              7100 6900 0210   18  114 505
    COMMITTEE ASSESSMENT OF AEROBIOLOGICAL ISSUES          7100 6900 0212   27  114 505
                                                           7100 6900 0213   13  114 505
    TBD                  WALLIN  JACK R          76/06/25  7100 6900 2020   14  114 505
    0043241                                      79/06/25  7100 6900 2320   18  114 505
                                                           7200 6900 2740   10  114 505
                                                                                    SUM

    3090-20231-001      FARGO              ND              4500 2100 0414  100  207 310     16,110
    RADIOBIOLOGY, MICROBIOLOGY, AND GENETICS OF BULL W                              SUM     16,110
I   EEVIL COLONIES FOR STERILE RELEASE PROGRAMS
    FRYE  R D            LEOPOLD  R A            76/06/01
    0043093              NORTH  D T              78/05/31

    3202-20420-043      AMES, IA                           4600 3000 0710   60  211 401                           48,759     .21
NI  BIOLOGICAL EFFECTS OF SOLAR (UV-B) RADIATION ON EY     4890 3100 0210   13  213 402                           10,564     .05
    E AND SKIN CANCER AND OTHER LIVESTOCK DISEASES         4890 3100 1110   27  213 402                           21,942     .10
    PUGH  G W JR         KOPECKY  K E            76/12/16                           SUM                           81,265     .36
    0043545              HUGHES  D E             78/06/16

    3508-20450-011      EAST LANSING, MI                   4600 2900 0110   25  211 403     23,542      .20       24,954     .19
I   IDENTIFICATION OF AVIAN LEUKOSIS VIRUSES BY RADIOI     4600 2900 0510   25  211 403     23,542      .20       24,954     .19
    MMUNOASSAY                                             4600 2900 0610   25  211 403     23,542      .20       24,954     .19
    SMITH  E J                                   74/12/13  4600 2900 1410   25  211 403     23,542      .20       24,954     .19
    0042008                                      77/12/13                           SUM     94,167      .80       99,816     .76

    3602-20250-005      FARGO, ND                          4900 6500 0410   15  318 701     34,853      .37       53,891     .48
I   RADIATION AND CHEMICAL STERILIZATION OF INSECTS        4900 6500 0412   60  318 701    139,411     1.47      215,562    1.93
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6/06/77                                  (CC)  CLASSIFICATIUN DATA, FUNDS AND SY AS OF  00000                             PAGE      3
                                    ARS PROJECTS USING NUN-IUNIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                                    LAST YR                  THIS YR
                   DETAIL LINES                          ACTI COMM SCIE TOT % RPA RP    ACTUAL $       SY     PLANNED $       SY
                                                         4900 6500 0513  25  318 701      58,088       .61       89,818       .80
  LACHANCE  L E        PROSHULD  F I         75/05/28                            SUM     232,352      2.45      359,270      3.21
  0042456              NORTH  D T            80/05/28

  3602-20250-006       FARGO, ND                         4900 6500 0410  40  318 701      52,859       .65       32,066       .32
I FACTORS AFFECTING REPRODUCTIVE FITNESS OF COLONIZE     4900 6500 0412  40  318 701      52,859       .65       32,066       .32
  D INSECTS                                              4900 6500 0513  20  318 701      26,429       .33       16,033       .16
  LACHANCE  L E        RIEMANN  J G          75/05/28                            SUM     132,147      1.63       80,165       .80
  0042457              UEGHUGILLIER  M E     80/05/28

  5602=20160=002       FORT COLLINS, CO                  5000 6700 0212  35  307 701      16,572       .17       42,467       .24
I ENVIRONMENTAL AND UTHER FACTOR EFFECTS UPON SEED V     4900 6200 1312  50  318 701      23,675       .24       60,667       .35
  IABILITY AND STORAGE                                   5000 6700 0212  15  304 701       7,102       .07       18,200       .10
  BASS  L N            ROUS  E E             76/01/16                            SUM      47,349       .48      121,334       .69
  0042921                                    81/01/16

I 5602-20160-003       FORT COLLINS, CO                  4900 6200 0512  50  318 701       7,892       .08       26,377       .15
  GENETIC CHANGES IN SEEDS DURING STORAGE                4900 6200 1312  50  318 701       7,892       .08       26,377       .15
                                                                                 SUM      15,783       .16       52,754       .30
  ROOS E E                                   76/01/16
  0042922                                    81/01/16

I 5602-20760-001       FORT COLLINS, CO                  4300 0200 2421  60  105 102      30,697       .54       29,181       .21
  MEASUREMENT AND PREDICTIUN UF SUIL WATER MUVEMENT      4300 0200 2420  20  105 102      10,232       .18        9,727       .07
                                                         4300 0200 2220  20  105 102      10,232       .18        9,727       .07
  KLUTE  A             HEERMANN  D F         68/03/21                            SUM      51,162       .90       48,635       .35
  0018640                                    77/11/14

  5703-20020-001       ABERDEEN, ID                      4600 1100 0512  15  205 314       4,443       .11       15,343       .27
I BREEUING HIGH-QUALITY POTATOES FOR THE WESTERN UNI     4600 1100 1112  15  205 314       4,443       .11       15,343       .27
  TED STATES                                             4840 1100 0512  10  206 314       2,962       .08       10,229       .18
  PAVEK  J J           CORSINI  D L          69/05/21    4870 1100 1112  10  404 314       2,962       .08       10,229       .18
  0017817                                    81/12/23    4870 1100 0512  10  404 314       2,962       .08       10,229       .18
                                                         4900 1100 0512  10  402 314       2,962       .08       10,229       .18
                                                         5000 1100 0512  30  304 314       8,887       .23       30,687       .54
                                                                                 SUM      29,622       .75      102,289      1.80

  5709-20360-001       MILES CITY, MT                    5000 3000 0110  20  310 401      49,077       .47
I IMPROVING REPRODUCTIVE EFFICIENCY IN RANGE BEEF CA     5000 3000 0510  10  311 401      24,538       .23
  TTLE                                                   5000 3000 0910  20  311 401      49,077       .47
  BELLOWS  R A         SHORT  R E            63/08/30    5000 3000 1310  50  310 401     122,692      1.17
  0015884              RANDEL  R D           79/02/14                            SUM     245,384      2.33

I 7091-20230-003       BATON ROUGE       LA              4500 2100 0412  50  207 310      13,885
  RAPID STERILIZATION OF THE BOLL WEEVIL WITH CHEMOS     4500 2100 1310  50  207 310      13,885
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    6/06/77                             (CC)  CLASSIFICATION DATA, FUNDS AND SY AS OF  00000                       PAGE      4
                                ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                                          LAST YR                 THIS YR
                       DETAIL LINES                    ACTI COMM SCIE TOT % RPA RP       ACTUAL $        SY      PLANNED $        SY

    TERILANTS AND GAMMA IRRADIATION                                              SUM        27,770
    NEWSOM  L D          EARLE  N W           75/06/26
    0042583                                   77/09/30
    EXTRAMURAL FUNDS: 0018500

    7307-20760-003       TEMPLE, TX                        4300 0100 2420   13  102 101        16,582       .14         20,634       .16
    MODELING SOIL-PLANT-ATMOSPHERE RELATIONS FOR AGRIC 4300 0100 2120   13  102 101        16,582       .14         20,634       .16
NI  ULTURAL PLANT COMMUNITIES                          4300 0100 2320   13  102 101        16,582       .14         20,634       .16
    RITCHIE  J T                              74/11/15 4300 0100 1312   13  102 101        16,582       .14         20,634       .16
    0041853                                   79/11/15 4300 0200 2120   12  106 102        15,306       .13         19,047       .14
                                                       4300 0200 2420   12  107 102        15,306       .13         19,047       .14
                                                       4300 0400 2320   24  109 105        30,612       .27         38,094       .29
                                                                                 SUM       127,551      1.10        158,725      1.20

    7413-20230-001       BATON ROUGE, LA               4500 2100 0412   50  207 310        56,228       .83         76,676      1.20
    PRODUCTION OF STERILE BOLL WEEVILS SUITABLE FOR PU 4500 2100 1310   50  207 310        56,228       .83         76,676      1.20
I   PULATION SUPPRESSION IN THE  FIELD                                           SUM       112,456      1.67        153,352      2.40
    EARLE  N W           VILLAVASO  E J       74/08/26
    0041751                                   76/08/26

    7413-20230-005       BATON ROUGE, LA               4500 2100 0412   50  207 310
    DEVELOPMENT OF NEW TECHNIQUES FOR STERILIZING BOLL 4500 2100 1310   50  207 310
     WEEVILS                                                                     SUM
I   EARLE  N W           VILLAVASO  E J       77/01/27
    0043643                                   79/01/27

    7502-20300-001       MISSISSIPPI ST., MS           4500 2100 1920   90  207 310        68,736       .81        305,429       .90
    DEVELOP EQUIPMENT AND METHODS TO MECHANIZE MASS RE 4500 2100 0414   10  207 310         7,637       .09         33,937       .10
I   ARING AND STERILIZATION OF BOLL WEEVILS                                      SUM        76,373       .90        339,365      1.00
    GRIFFIN  J G                              76/03/05
    0042979                                   81/03/05

    7602-20302-001       GAINESVILLE, FL               4900 6500 1920  100  318 701       211,263      3.00        233,367      3.00
    INSECT BEHAVIOR IN RESPONSE TO ELECTROMAGNETIC RAD                           SUM       211,263      3.00        233,367      3.00
NI  IATION AND SOUND WAVES
    STANLEY  J M         TURNER  W K          74/08/13
    0041468              WEBB  J C            78/08/13

    7616-20620-001       MIAMI, FL                     4500 0900 0412  100  204 313       274,662      1.86        251,713      3.00
I   COMMODITY TREATMENTS FOR FLORIDA FRUIT FLIES                                 SUM       274,662      1.86        251,713      3.00

    BURDITT  A K JR                           74/03/29
    0040969                                   77/03/29

I   7619-20851-001       ST. CROIX, VI                 4500 4000 0413  100  706 504       136,315                   137,322
    BIOLOGICAL CONTROL OF STABLE FLIES ON ST. CROIX                              SUM       136,315                   137,322
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   6/06/77                     (CC)  CLASSIFICATION DATA, FUNDS AND SY AS OF  00000                         PAGE    5
                          ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                            LAST YR                  THIS YR
                 DETAIL LINES                 ACT1 COMM SCIE TOT % RPA RP    ACTUAL $      SY       PLANNED $      SY

   PATTERSON  R S       WILLIAMS  D F       75/05/09
   0042432                                  78/05/09

I  7619-20859-001       ST. CROIX, VI       4830 0100 0413  100   901 104      69,098     1.10        86,399     1.00
   CONTROL OF THE STABLEFLY STOMOXYS CALCITRANS                        SUM      69,098     1.10        86,399     1.00

   LABRECQUE  G C       WILLIAMS  D F       75/05/23
   0042448                                  78/05/23

NI 7702=20190=013       TIFTON, GA          5200 1400 1920   30   308 301
   MICROWAVE-VACUUM SYSTEM FOR DRYING FARM CROPS                 5200 1500 1920   10   308 302
                                            5200 2300 1920   10   308 306
   BUTLER  J L                          77/03/29 5200 2400 1920   20   308 307
   0043709                              79/03/29 5200 2800 1920   30   308 312
                                                                      SUM

I  7705-20620-002       SAVANNAH, GA        4500 1000 0412   60   404 313      19,658      .38
   EFFECTS OF GAMMA RADIATION ON BEHAVIOR, ECOLOGY, A 4500 1200 0412   40   404 314      13,106      .25
   ND GENETICS OF  STORED-PRODUCT INSECTS                              SUM      32,764      .64
   BROWER  J H                          74/11/15
   0041803                              77/11/15

NI 7705-20620-004       SAVANNAH, GA        4500 1400 0412   10   408 301       3,680      .05
   BEHAVIORAL EFFECTS OF NONIONIZING ELECTROMAGNETIC 4500 1500 0412   10   408 302       3,680      .05
   RADIATION ON STORED-PRODUCT INSECTS      4500 1700 0412   30   408 303      11,039      .16
   BRUCE  W A                           74/11/15 4500 2300 0412   10   408 306       3,680      .05
   0041811                              78/11/15 4500 2400 0412   40   408 307      14,719      .21
                                                                      SUM      36,797      .54

I  7705-20620-015       SAVANNAH, GA        4500 1400 0412   20   408 301      29,438      .43        34,637      .45
   INTRODUCED STERILE POPULATIONS TO CONTROL MOTHS IN 4500 1700 0412   10   408 303      14,719      .21        17,319      .23
    STORED COMMODITIES                      4500 2400 0412   70   408 307     103,033     1.50       121,230     1.58
   TILTON  E W          BROWER  J H     74/11/26                          SUM     147,190     2.14       173,185     2.26
   0041931              VARDELL  H H    78/11/26

NI 7902-20600-002       ATHENS, GA          4600 2900 0710   42   412 403      28,762      .43        34,385      .46
   IMPROVEMENT OF POULTRY AND PORK PLANT EQUIPMENT CL 4600 3200 0710   18   412 405      12,327      .18        14,736      .20
   EANING BY ULTRASONICS AND OTHER METHODS  5500 2900 1920   28   410 403      19,175      .28        22,923      .31
   THOMSON  J E         SHACKELFORD  A D 75/11/21 5500 3200 1920   12   410 405       8,218      .12         9,824      .13
   0042870                              78/11/21                          SUM      68,481     1.01        81,868     1.10

I  7902-20832-004       ATHENS, GA          4880 2600 1524  100   709 311     115,807     1.54        90,172     1.29
   RADIATION EFFECTS ON TOBACCO AND TOBACCO SMOKE                      SUM     115,807     1.54        90,172     1.29

   CHORTYK  O T                         73/03/22
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6/06/77                         (CC)  CLASSIFICATION DATA, FUNDS AND SY AS OF  00000                     PAGE       6
                          ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION

                                                                              LAST YR              THIS YR
              DETAIL LINES                    ACTI COMM SCIE TOT % RPA RP    ACTUAL $     SY      PLANNED $     SY
0040163                        78/03/22

                                                                             2,030,461   29.56   3,109,710    29.11
FINAL TOTALS                                                                 2,030,461   29.56   3,109,710    29.11

     250   RECORDS TOTALED

PAGE   1     RADCC/TXT

   1.  //ARS1PACA  JOB  (1402045366,RJ066),'JANSEN',CLASS=C,TIME=(,19)
   2.  //  EXEC ARPARIS
   3.  //SYSIN DD *
   4.  CC
   5.  INCLUDE COFUNDS
   6.  IF ORGN GO 0000
   7.  FLUNK
   8.  INCLUDE TITLE = RADIA
   9. G O TO JNS
  11.  GO TO JNS
  12.  IF CWU = 109020611001,109020831003,109020911005,110920172004,770220190013
  13.  OR CWU = 790220600002
  14.  GO TO JNS
  15.  IF SPCP5 = 000,*
  16.  FLUNK
  17.  JNS: IF 1 = 1
  18.  IF CWU = 760220302001 THEN LYA01 = 211263
  19. LYATFUNDS =  211263
  21.  LYATSH = 6288
  22.  IF A9 = A9
  23.  T2ARS PROJECTS USING NON-IONIZING AND RADIOACTIVE SOURCES OF RADIATION
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6/06/77

ARS RADIATION RESEARCH USING NON-IONIZING AND RADIOACTIVE (*) SOURCES
FY 76 & 77 PROPORTIONED FUNDS BY TYPE AND SCIENTIST YEARS ----INTRAMURAL

PAGE 1

	CRIS WORK UNIT	"RAD" PCT	76 REG FUNDS	76 REIMB FUNDS	76 TOTAL FUNDS	76 TOT SY'S	77 REG FUNDS	77 REIMB FUNDS	77 TOTAL FUNDS	77 TOT SY'S
NI	1109-20172-004	100	114,106		114,106	.63	45,800		45,800	.35
	NRP TOTAL		114,106		114,106	.63	45,800		45,800	.35
NI	1109-20193-001	100	27,054		27,054	.29	12,046		12,046	.13
NI	7702-20190-013	100				.00				.00
	NRP TOTAL		27,054		27,054	.29	12,046		12,046	.13
NI	7602-20302-001	100	211,263		211,263	3.00	233,367		233,367	3.00
	NRP TOTAL		211,263		211,263	3.00	233,367		233,367	3.00
I	1106-20392-005	100	29,360		29,360	.18	37,800		37,800	.32
	NRP TOTAL		29,360		29,360	.18	37,800		37,800	.32
NI	3202-20420-043	100				.00	47,065	34,200	81,265	.36
	NRP TOTAL					.00	47,065	34,200	81,265	.36
I	3508-20450-011	100	94,167		94,167	.80	99,816		99,816	.76
	NRP TOTAL		94,167		94,167	.80	99,816		99,816	.76
NI	7902-20600-002	100	68,481		68,481	1.01	81,868		81,868	1.10
	NRP TOTAL		68,481		68,481	1.01	81,868		81,868	1.10
NI	7705-20620-004	100	36,797		36,797	.54				.00
	NRP TOTAL		36,797		36,797	.54				.00
I	7902-20832-004	100	115,807		115,807	1.54	90,172		90,172	1.29
	NRP TOTAL		115,807		115,807	1.54	90,172		90,172	1.29
	RADIATION TYPE		697,035		697,035	7.99	647,934	34,200	682,134	7.31
I	5703-20020-001	*010	2,962		2,962	.08	10,229		10,229	.18
	NRP TOTAL		2,962		2,962	.08	10,229		10,229	.18
I	1108-20100-002	*010	7,585		7,585	.09	11,833		11,833	.10
I	1108-20101-002	*010	4,820		4,820	.05	7,420		7,420	.06
	NRP TOTAL		12,405		12,405	.14	19,253		19,253	.16
I	5602-20160-002	*005	2,367		2,367	.02	6,067		6,067	.03
I	5602-20160-003	*005	789		789	.01	2,638		2,638	.02
	NRP TOTAL		3,156		3,156	.03	8,705		8,705	.05
I	7413-20230-001	*005	5,623		5,623	.08	7,668		7,668	.12
I	7413-20230-005	*005				.00				.00
	NRP TOTAL		5,623		5,623	.08	7,668		7,668	.12
I	3602-20250-005	*075	148,666	25,598	174,264	1.84	240,496	28,957	269,453	2.41
I	3602-20250-006	*040	52,859		52,859	.65	32,066		32,066	.32
	NRP TOTAL		201,525	25,598	227,123	2.49	272,562	28,957	301,519	2.73
I	7502-20300-001	*010	7,637		7,637	.09	33,937		33,937	.10
	NRP TOTAL		7,637		7,637	.09	33,937		33,937	.10

I - Ionizing radiation

NI - Non-ionizing radiation

6/06/77

ARS RADIATION RESEARCH USING NON-IONIZING AND RADIOACTIVE (*) SOURCES
FY 76 & 77 PROPORTIONED FUNDS BY TYPE AND SCIENTIST YEARS ----INTRAMURAL

PAGE 2

	CRIS WORK UNIT	"RAD" PCT	76 REG FUNDS	76 REIMB FUNDS	76 TOTAL FUNDS	76 TOT SY'S	77 REG FUNDS	77 REIMB FUNDS	77 TOTAL FUNDS	77 TOT SY'S
I	5709-20360-001	*020	49,077		49,077	.47				.00
	NRP TOTAL		49,077		49,077	.47				.00
I	7616-20620-001	*020	54,932		54,932	.37	50,343		50,343	.60
I	7705-20620-002	*100	32,764		32,764	.64				.00
I	7705-20620-015	*100	147,190		147,190	2.14	173,185		173,185	2.26
	NRP TOTAL		234,886		234,886	3.15	223,528		223,528	2.86
I	5602-20760-001	*010	4,893	223	5,116	.09	3,704	1,160	4,864	.03
NI	7307-20760-003	*025	31,888		31,888	.28	39,681		39,681	.30
	NRP TOTAL		36,781	223	37,004	.37	43,385	1,160	44,545	.33
I	1103-20791-001	*100	98,733	60,233	158,966	2.15	125,664	21,939	147,603	2.14
	NRP TOTAL		98,733	60,233	158,966	2.15	125,664	21,939	147,603	2.14
I	7619-20851-001	*050	68,158		68,158	.00	68,661		68,661	.00
I	7619-20859-001	*050	34,549		34,549	.55	43,200		43,200	.50
	NRP TOTAL		102,707		102,707	.55	111,861		111,861	.50
	RADIATION TYPE		755,492	86,054	841,546	9.60	856,792	52,056	908,848	9.17
	IN-H/EXML TOTAL		1,452,527	86,054	1,538,581	17.59	1,504,726	86,256	1,590,982	16.48

6/06/77 ARS RADIATION RESEARCH USING NON-IONIZING AND RADIOACTIVE (*) SOURCES PAGE 3
FY 76 & 77 PROPORTIONED FUNDS BY TYPE AND SCIENTIST YEARS ----EXTRAMURAL

	CRIS WORK UNIT	"RAD" PCT	76 REG FUNDS	76 REIMB FUNDS	76 TOTAL FUNDS	76 TOT SY'S	77 REG FUNDS	77 REIMB FUNDS	77 TOTAL FUNDS	77 TOT SY'S
I	3090-20231-001	100	16,110		16,110	.00				.00
	NRP TOTAL		16,110		16,110	.00				.00
NI	1090=20611=001	100	11,567		11,567	.00				.00
	NRP TOTAL		11,567		11,567	.00				.00
I	1090-20781-002	100	34,701		34,701	.00				.00
	NRP TOTAL		34,701		34,701	.00				.00
I	1090-20831-003	100				.00	22,930		22,930	.00
	NRP TOTAL					.00	22,930		22,930	.00
NI	1090-20911-005	100	38,055		38,055	.00				.00
	NRP TOTAL		38,055		38,055	.00				.00
	RADIATION TYPE		100,433		100,433	.00	22,930		22,930	.00
—	3090-20041-005	*010				.00				.00
	NRP TOTAL					.00				.00
I	7091-20230-003	*020	5,554		5,554	.00				.00
	NRP TOTAL		5,554		5,554	.00				.00
	RADIATION TYPE		5,554		5,554	.00				.00
	IN-H/EXML TOTAL		105,987		105,987	.00	22,930		22,930	.00

6/06/77 ARS RADIATION RESEARCH USING NON-IONIZING AND RADIOACTIVE (*) SOURCES PAGE 4
FY 76 & 77 PROPORTIONED FUNDS BY TYPE AND SCIENTIST YEARS ----EXTRAMURAL

CRIS WORK UNIT	"RAD" PCT	76 REG FUNDS	76 REIMB FUNDS	76 TOTAL FUNDS	76 TOT SY'S	77 REG FUNDS	77 REIMB FUNDS	77 TOTAL FUNDS	77 TOT SY'S
FINAL TOTALS		1,558,514	86,054	1,644,568	17.59	1,527,656	86,256	1,613,912	16.48

36 RECORDS TOTALED

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PAGE    1     RADPROP/TXT

 SUPPRESS
 *++RADIA START
 PARISRA IS
 DATA 15 40 A LYATSY 15 5 N2 TSY 20 5 N2 PCT 25 3 NO TP 28 1 A TYPE 30 10 A
 RDP 40 4 A RDP1 40 1 A RDP2 41 3 A
 INCLUDE DICT
 9999
 IF SORTED = YES
 B9 = XOC
 SUCCESS
INCLUDE E CLUDE
 FLUNK
 GO TO A1
 INCLUDE TITLE = RADIO
 GO TO A1
 IF CWU = 109020611001,109020831003,109020911005,110920172004,770220190013
 OR CWU = 790220600002
 GO TO A1
 IF SPCP5 = 000,*
 FLUNK
 A1: IF A9 = A9
 INCLUDE COFUNDS
DA * =  *
 IF SPCP5 NO 000          THEN RDP2 = SPCP5
 IF SPCP5 NO 000          THEN RDP1 = (*)
 RDP2 = SPCP5
 IF SPCP5 = 000,*          THEN RDP2 = 100
 IF CWU = 760220302001      THEN LYA01 = 211263
 LYATFUNDS = 211263
 LYASH01 = 6288
 LYATSH = 6288
 IF A9 = A9
 PCT = RDP2
 LYA01 = LYA01 X PCT + 50 / 100
 LYA08 = LYA08 X PCT + 50 / 100
 LYATFUNDS = LYATFUNDS X PCT + 50 / 100
 PL01 = PL01 X PCT + 50 / 100
 PL08 = PL08 X PCT + 50 / 100
 TFUNDS = TFUNDS X PCT + 50 / 100
 LYATSY = LYATSH X PCT X 10 / 2096 + 5 / 10
 TSY = TSH X PCT X 10 / 2100 + 5 / 10
 IF PRTP = D         THEN TP = A
 TYPE = (INTRAMURAL)
 IF PRTP NO D         THEN TP = B
 TYPE = (EXTRAMURAL)
 B9=  XOC
 CONTROLS NRPS 'NRP*TOTAL' RDP1 'RADIATION*TYPE' TYPE-E '(IN-H/EXM
 T2-63 EQ TYPE
 T1 -ARS RADIATION RESEARCH USING NON-IONIZING AND RADIOACTIVE (*) SOURCES
 T2FY 76 & 77 PROPORTIONED FUNDS BY TYPE AND SCIENTIST YEARS ----
 LIST LJ DETAIL SPACE 2 CWU 'CRIS*WORK*UNIT' RDP '("RAD"),PCT'  MORE
 LYA01 '76*REG,FUNDS' LYA08 '76*REIMB,FUNDS' LYATFUNDS '76*TOTAL,FUNDS'  MORE
 LYATSY '76*TOT,(SY'S)' PL01 '77*REG,FUNDS' PL08 '77*REIMB,FUNDS' MORE
 TFUNDS '77*TOTAL,FUNDS' TSY '77*TOT,(SY'S)'
 *++RADIA END
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NATIONAL TRANSPORTATION SAFETY BOARD,
Washington, D.C., June 3, 1977.

Hon. ADLAI E. STEVENSON,
Chairman, Science, Technology and Space Subcommittee, Senate Committee on Commerce, Science, and Transportation, Washington, D.C.

DEAR MR. CHAIRMAN: With reference to your letter of May 19, the National Transportation Safety Board's activities do not include either radiation research or radiation regulation.

A similar reply is being sent to the Chairman of the Consumer Subcommittee.

Sincerely yours,

KAY BAILEY,
(For Webster B. Todd, Jr., Chairman).

U.S. DEPARTMENT OF THE INTERIOR,
MINING ENFORCEMENT AND SAFETY ADMINISTRATION,
Arlington, Va., June 7, 1977.

Hon. WENDELL H. FORD,
Chairman, Subcommittee on Consumers, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR SENATOR FORD: This is in response to your letter of May 20, co-signed by the Honorable Adlai E. Stevenson, Chairman of the Subcommittee on Science, Technology, and Space, concerning radiation control.

The Mining Enforcement and Safety Administration (MESA) is responsible for administering the Federal Metal and Nonmetallic Mine Safety Act and the Federal Coal Mine Health and Safety Act of 1969. The major radiation exposure under MESA's jurisdiction occurs with uranium miners. These miners are exposed to ionizing radiation from natural radioactivity. MESA promulgates standards for occupational exposure and also conducts inspections to determine compliance with such standards. We have completed the matrices that you provided in your request, but we are unable to identify the number of positions and funds expended on radiation since it is part of our overall enforcement program. Because of our inability to provide the data asked for, we have added footnotes to the matrices to explain our activities under each column.

The following responses are to the specific questions in your letter.

1. What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Answer. The Federal Coal Mine Health and Safety Act of 1969 changed our jurisdiction and operations, but this change did not affect our overall efforts in radiation areas since coal mines do not have significant radiation sources.

2. Would you please describe the nature of the contacts between your organization and state groups in the radiation field? Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

Answer. Under the Federal Metal and Nonmetallic Mine Safety Act, the Secretary of the Interior is authorized to enter into State Plan agreements. Under these provisions, MESA has agreements with six States including the major uranium-producing States of Colorado, New Mexico, and Utah. There is no confusion concerning respective responsibilities between the States and MESA.

3. Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved? Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

Answer. The one deficiency that MESA views as most serious is the lack of research in the areas of detection of incipient lung cancer from radiation exposures in mining. Research in these areas has been fragmented among several agencies—National Cancer Institute, National Institute of Occupational Safety and Health (NIOSH), and Energy Research and Development Administration (ERDA). Another deficiency that makes it difficult to determine the magnitude of the problems is the lack of a better method of tracking miners that will allow an accurate determination of cancer incidence. This problem is related to epidemiology and would logically be conducted by NIOSH.

4. What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

Answer. MESA does not believe that consolidation of all radiation activities within one agency would be prudent. For example, as an occupational hazard, it is no different than exposure to any number of other toxic and harmful substances. As such, MESA can enforce standards for occupational exposure as an adjunct to inspection for other health and safety problems. Consolidation would create another Federal agency for mine operators to contend with if radiation were separated from other health and safety issues. We believe also that certain research problems, such as we have outlined above, can be treated effectively by more than one agency with proper coordination. We have had satisfactory working relations with all other Federal agencies involved in radiation regulations.

I trust the information provided herein answers your questions. If I can be of any further service, please do not hesitate to let me know.

Sincerely yours,

ARTHUR P. NELSON,
(For Robert E. Barrett, Administrator).

Enclosures.

IONIZING RADIATION

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies(explain)	Other Studies (Explain)
1968 In-House (Positions)	None	None	None	Footnote (1)	Footnote (2)	Footnote (3)	None	None	Footnote (4)	(5) Footnote	None	(6) Footnote
1969 Extra-Mural (Funds) Total Funds												
1970												
1971												
1972												
1973												
1974												
1975												
1976												
1977												
Est. 1978												

applies to all years

NON-IONIZING RADIATION (Identify type of non-ionizing radiation e.g. microwave, ultrasound, etc.)

Year	Studies to determine human health effects	Ecological efforts Animal Plant	Agricultural Effects Plant/Animl	Criteria and/or Standards Develpmt	State/ Federal Liaison	Licensing, Certification, Inspection	Monitoring and/or Surveillance	Medical Diagnostic Therapeutic	Collection and/or analysis of health data	Collection and/or analysis of environmntl data	Other biological or physical effects studies (explain)	Other Studies (Explain)
1968 In-House (Positions)	None	None	None	(1)	(2)	(3)	None	None	(4)	None	None	None
1969 Extra-Mural (Funds) Total Funds	↓	↓	↓					↓		↓	↓	↓
1970	↓	↓	↓					↓		↓	↓	↓
1971	↓	↓	↓					↓		↓	↓	↓
1972	↓	↓	↓					↓		↓	↓	↓
1973	↓	↓	↓					↓		↓	↓	↓
1974	↓	↓	↓					↓		↓	↓	↓
1975	↓	↓	↓					↓		↓	↓	↓
1976	↓	↓	↓					↓		↓	↓	↓
1977	↓	↓	↓					↓		↓	↓	↓
Est. 1978	↓	↓	↓					↓		↓	↓	↓

applies to all years

Footnotes to matrices

1. MESA has developed standards for occupational exposure to natural radiation. These standards are based on guidance provided by the Environmental Protection Agency and approved by the President. We are continually reviewing and analyzing our standards for their adequacy and effectiveness.

2. MESA has State Plans with the States of Arizona, Colorado, New Mexico, North Carolina, Utah, and Virginia. These Plans were entered into under the provisions of the Federal Metal and Nonmetallic Mine Safety Act.

3. MESA and the State Plan States conduct a program of inspection to assure that radiation exposures do not exceed applicable standards.

4. MESA has a mandatory requirement for mine operators to report on occupational injuries and illnesses occurring among miners. Although lung cancer caused from radiation should be reported, it seldom is. Because lung cancer is a debilitating disease, mine worker victims of lung cancer usually are not employed by mining companies at the time that their disease is diagnosed. There is a reluctance by mine operators to assume liability, and such cases of lung cancer are rarely reported to MESA. The same is true of other occupational illnesses requiring long periods of latency from first exposure to recognition of disease.

5. MESA collects mine environmental data during the course of its inspections. Such data consist of radiation concentrations in working areas of active mines.

6. MESA is conducting studies of improved instrumentation and dosimetry for measuring radiation levels and exposure in mines. MESA also conducts studies on methods for controlling exposure in mines.

SMITHSONIAN INSTITUTION,
Washington, D.C., June 2, 1977.

Hon. ADLAI E. STEVENSON,
U.S. Senate,
Washington, D.C.

DEAR SENATOR STEVENSON: I am replying to your and Senator Ford's letter of May 20, 1977, requesting information from the Smithsonian on the research done in its laboratories which involve the use of radioactive substances.

The Smithsonian's Radiation Biology Laboratory uses C_{14}, Tridium and P_{32} in quantities of micro- and millicuries as radioactive tracers in botanical experiments. The total amount used each year of all three together would add to less than one curie.

The research at the Chesapeake Bay Center may use one or two tenths of a curie in a busy year, but are now using no radioactive tracers.

With reference to the questions asked, the changes in jurisdiction have had no effect on our operations. The only contact we have with state groups is when we get a routine permit from Maryland for the use of isotopes at the Radiation Biology Labortory in Rockville. We have no problem with the present regulations as they affect our use of radioactive substances and we use so little that we do not have any feeling one way or another about the proposals to consolidate all federal radiation activities into one federal radiation agency.

Sincerely yours,

S. DILLON RIPLEY,
Secretary.

DEPARTMENT OF THE INTERIOR,
BUREAU OF MINES,
JUNE 6, 1977.

Hon. ADLAI E. STEVENSON,
Chairman, Subcommittee on Science, Technology, and Space, Committee on Commerce, Science, and Transportation, U.S. Senate Washington, D.C.

DEAR SENATOR STEVENSON: This letter is in reply to your request of May 20, 1977, for information on the Bureau of Mines program on radiation research. The enclosed matrices have been completed as requested in your letter. A short description of the Bureau's radiation hazards research program is also enclosed:

Your letter requested written response to four questions. The questions and our response to them are as follows:

(1) What changes in jurisdiction between 1968 and 1977 have affected your organization's responsibilities (i.e., inception of new agencies, transfers of regulatory authority, etc.)? How have these changes affected your overall efforts in the radiation area?

Regulatory authority for health and safety in mines including radiation hazards was transferred from the Bureau of Mines to the Mining Enforcement and Safety Administration (MESA) in 1973. The Bureau of Mines retained responsibility for mining health and safety research and conducts a small research program on radiation hazards in mines. The objective of this program is the reduction of exposure of uranium miners to radon gas and its airborne daughters through the development of improved technology for the measurement and control of these hazards in mines. The Bureau is developing the testing radiation dosimeters in close cooperation with MESA with the intention that the dosimeters will eventually be used for enforcement of radiation standards in underground mines. The Bureau provides input to MESA for the development of new regulations concerning mine health and safety, including radiation hazards. MESA suggests new research projects needed for development of, or compliance with, health and safety regulations and helps evaluate proposed research projects each fiscal year using a standard methodology. Because of this close cooperation between the Bureau of Mines and MESA, there has been no adverse effect on the radiation research program due to the transfer of the regulatory authority to MESA.

(2) Would you please describe the nature of the contacts between your organization and state groups in the radiation field. Under what conditions, if any, are you required to contact or coordinate with state agencies? Is there any confusion concerning respective responsibilities of state and federal agencies?

The Bureau of Mines contacts state mine inspectors concerning any new radiation research projects which will be conduted in mines in their state. The Bureau also requests input on research needs from the state mine inspectors. There is no real confusion concerning responsibilities of state agencies and the Bureau of Mines in the radiation field, since the state agencies do very little, if any, research on radiation hazards in mines.

(3) Would you please provide the Committee with your thoughts on how the present regulation of radiation programs could be improved. Are there any present deficiencies of such regulation which you believe deserve priority attention? Do you believe the present funding levels in this area are adequate?

We believe that the present division of responsibility for mining radiation regulation and research between the Bureau of Mines and MESA is satisfactory. We recognize certain deficiencies in the determination of compliance with radiation standards in uranium mines due to a lack of accurate and reliable methods of measurement for this purpose. The Bureau is developing and testing radon daughter dosimeters which should help to overcome this problem. Development of radon daughter dosimeters is the top priority of our radiation hazards research program. Testing of the dosimeters is being done in cooperation with MESA and the Bureau will work with MESA on the development of regulations for the use of dosimeters in uranium mines. Funding for development and testing of the dosimeters is adequate. However, it is expected that implementation of the dosimeters may show that actual radon daughter levels in uranium mines may need to be reduced. For this reason increased funding for research to control radon and its daughters in uranium mines woul be very worthwhile.

(4) What is your reaction to the proposals to consolidate all federal radiation activities into one federal radiation agency?

We would be opposed to complete consolidation of all federal radiation activities into one radiation agency. Any needles duplication of effort or division of responsibility should be eliminated. However, radiation research and regulation of radiation hazards in mines is primarily a mining rather than a radiation problem. Methods for the control of radon and its daughters must fit into the mining system in a practical way so that ore can be produced economically while maintaining a safe mine environment. Radiation instrumentation must also be suitable for use under the rugged conditions encountered in mines. Radiation research in mines, as with all mine health and safety research, is best done by one federal mining research organization rather than setting up a new mining research organization in any new federal radiation agency.

I hope that the information provided with this letter is sufficient. We will be happy to provide any additional information which you may need in the course of your review of federal radiation programs.

Sincerely yours,

J. D. MORGAN, *Acting Director.*

RADIATION HAZARDS RESEARCH PROGRAM

Extensive exposure to radiation hazards found in uranium mines is a major health problem to miners. Studies indicate that uranium miners have a nonviolent death rate 40 percent higher than the normal population. The objective of the Bureau's radiation hazards research program is the reduction of exposure of uranium mining personnel to radon gas and its airborne daughters by continuing to develop improved technology for the measurement and control of radiation hazards in mines. Development of a personal dosimeter for measurement of the exposure of miners to radon daughters continues to be the highest priority task. Currently under development or test are thermoluminescent type (TLD), electronic and track etch dosimeters. It is expected that MESA will require use of dosimeters in uranium mines by fiscal year 1980. Detectors for measurement of radon and other airborne alpha emitters in a mine environment are being developed. Ultimate results of this technology is the development of (1) a radiation warning system incorporationg a BOM developed continuous working level monitor to alert mine personnel to excessively high concentrations of radon daughters in selected mine areas; and (2) a portable radiation alarm to indicate unsafe levels of airborne radioactivity. Control technology R. & D. is underway on (1) sealants and bulkheading to prevent or reduce radon leakage into the ventilation system of a uranium mine; (2) ventilation pressure control to determine the extent of radon daughter reduction resulting from deliberate cyclic pressure variation in a mine and also the relative merit of operating uranium mines at a slightly elevated pressure versus a slightly reduced pressure; and (3) air cleaning to remove radon daughters from the mine air by mechanical or electrostatic air filters. Substantial effort is being directed toward identification of major sources of radon as created by the mining cycle and development of methods to effectively control radon leakage from tailings when used as backfill in active underground mines. Furthermore, a fundamental study is being carried out to define the interaction of radon with airborne particulate matter in order to assess the effect of particulate matter on the transport of radon.

U.S. CONSUMER PRODUCT SAFETY COMMISSION,
Washington, D.C., September 16, 1977.

HON. ADLAI E. STEVENSON,
Chairman, Technology and Space Subcommittee, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter, co-signed by Senator Wendell H. Ford, in which you request information on the Consumer Product Safety Commission's radiation research and regulatory programs. We apologize for the delay in responding to your letter.

The Consumer Product Safety Commission was created in 1973 under the enabling provisions of the Consumer Product Safety Act (CPSA) 15 U.S.C. 2051. At that time, several other statutes were transferred from other agencies to the administration of the Commission. Of the acts administered by the Commission, regulatory action with respect to radiation hazards could be taken under the CPSA and the Federal Hazardous Substances Act (FHSA).

The jurisdiction of the Commission over hazards from radiation is, however, limited in several respects. The FHSA authorizes the Commission to declare a radioactive substance to be hazardous, and to require labeling or to ban the substance if labeling is found to be inadequate. Such authority is specifically limited by a statutory exclusion of any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and any regulations issued under that Act. Similarly, Commission jurisdiction over consumer products under the CPSA does not include risks of injury that could be eliminated or reduced to a sufficient extent by actions taken under the Atomic Energy Act of 1954. In addition, the Commission has no authority under the CPSA to regulate any risk of injury associated with electronic product radiation emitted from an electronic product if such risk could be subject to regulation under the Public Health Service Act.

Because of the statutory limitations on the Commission's authority to regulate radiation hazards, jurisdiction would appear to remain only in the area of naturally occurring substances, such as radium. Consequently, the Commission has no regulatory programs or resaerch projects relating to radiation hazards. Therefore, we have not completed the matrix provided in your letter and have no recommendations to offer regarding the questions raised in items (1) through (4) in your letter.

I hope this information will be helpful to you. If we can be of further assistance, please let us know.

Sincerely,

S. JOHN BYINGTON, *Chairman.*

U.S. DEPARTMENT OF COMMERCE,
NATIONAL BUREAU OF STANDARDS,
Washington, D.C., October 19, 1977.

WENDELL H. FORD,
Chairman, Subcommittee on the Consumer, Committee on Commerce, Science, and Transportation, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter, co-signed with Senator Adlai E. Stevenson, dated September 29, 1977, which solicited comments on our current national ability to measure ionizing and nonionizing radiatio. This same letter of response is also being sent to Senator Stevenson.

You requested comments on our current ability to measure ionizing and nonionizing rediation, including areas of current weakness in our radiation measurement capabilities, and anticipated future needs. I am attaching to this letter detailed comments prepared by experts at NBS in response to your request. These comments describe the current status of the radiation measurement system and the present and future programs at NBS to develop measurement standards, expertise, and techniques to meet the needs of the system.

NBS has provided national reference standards and developed measurement methodologies for selected areas of radiation monitoring and control. The radioactivity standard reference materials produced and verified by NBS form the basis for radioisotope quality control in the Nation. Safe use of what are now low energy x-ray machines for radiation therapy (250 keV) is traceable to NBS standards. A standard source for use in industrial ultraviolet radiation applications has been developed. The measurement of electromagnetic radiation produced by distant sources, such as radar and television towers, is on a firm scientific basis.

As described in the attachments, we see the need to develop standards in fields where they do not exist, as, for example, to adequately monitor solar radiation, and to extend our capability to perform measurements from far-field regions to close to the source of radiation. However, even more important, since the need is more immediate, we must develop appropriate mechanisms to transfer these standards and capabilities to the radiation users, regulators, and researchers so that accurate measurements can be made for assurance of public safety.

Throughout these attached comments there is clear indication of substantial and growing need. One of the most perplexing specific problems is the lack of intermediate levels of dissemination through which NBS programs can reach the user level. As revealed during the hearings which your Committee held in June, this is also recognized as a significant problem by the Federal regulatory agencies. The logical structure appears to involve the states and through them to the county, city, and other user categories. Unfortunately the capabilities of state radiation control programs vary widely and appear to suffer more generally from lack of resources. It seems clear that more consideration must be given to building increased capability at the state level.

I would like to emphasize the need for a common measurement base of standards and methodologies coordinated by the National Bureau of Standards. The proliferation of regulatory agencies with interest in portions of the radiation measurement field can lead to procedural uncertainties as the manufacturer and the regulatory body monitor what is, after all, a uniquely characterizable physical quantity. For example, the Department of Defense, the Federal Aviation Administration, the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Food and Drug Administration are concerned with the effects of one or another aspect of microwave radiation. The setting of a tolerable radiation level is the proper responsibility of the agency with regulatory jurisdiction. The measurement methods used to monitor the levels should be traceable to the national standards maintained at NBS.

I appreciate the opportunity to offer these NBS comments on this subject of considerable national concern. It is my hope that they will be useful in the deliberations of the Senate Committee on Commerce, Science, and Transportation. Please feel free to call on me or members of my staff for any additional information we can provide.

Sincerely,

ERNEST AMBLER, *Acting Director.*

Attachment.

NBS STAFF COMMENTS ON THE NATIONAL RADIATION MEASUREMENT SYSTEM

(Prepared in response to inquiry of Senator Adlai E. Stevenson and Senator Wendell H. Ford, Committee on Commerce, Science, and Transportation. October 13, 1977)

The inquiry of Senators Stevenson and Ford requested specific NBS comments on areas of current weakness in our radiation measurements system, existing efforts to improve our measurement capabilities, and anticipated future needs. Comments will be offered in each of these three areas for the following specific types of radiation: ionizing, electromagnetic (microwave and radiofrequency), ultraviolet, and ultrasonic. Although these four types of radiation do not constitute the entire range of NBS programs in the general area of radiation measurement, they are highly representative of the national situation regarding capability to measure radiation.

Before commenting on specific types of radiation, it would be beneficial to examine some of the characteristics of the national radiation measurements system which are generally applicable to all types of radiation measurements. Many of the weaknesses are common to the various types of radiation, and the apparent solutions to present problems also follow common lines. From our viewpoint, those solutions can generally be categorized as physical standards, dissemination mechanisms, measurement assurance, and training.

The United States is presently faced with a general proliferation of devices and materials which emit various kinds of radiation at various levels of intensity. In some cases, we know the approximate level at which significant biological hazard begins. In other cases, this level is not reliably known and remains to be determined. In any case, the critical factor is the accuracy and reliability of the measurements which form the basis for determination of public safety. The general public deserves the right to assume that the various levels of government, collectively or individually, have sufficient capability to make those measurements required to assure the benefits of radiation without undue risk. Because of severe deficiencies in the national measurement system, this assumption is too frequently unjustified.

An ideal measurement system would be based on a complete set of physical standards maintained by NBS over the range of types, energies, and intensities of radiation encountered in the present national environment. Although some of these basic standards have served the country for many years and more are under development, a significant number of additional standards are badly needed. Examples include ultraviolet, neutron, and high-energy x-ray radiation.

Dissemination mechanisms serve as the linkage between the national physical standards and the field measurements made at the level of the radiation user. This generally involves calibration of radiation sources and measuring instruments against the national physical standards, and their transfer to the user level. Through this process, adequate accuracy and uniformity of field measurements can be achieved. Since NBS is physically incapable of calibrating the large numbers of existing field instruments, intermediate levels of calibration services are required for an effective national system. One of the most serious deficiencies in the present system is the lack of organizations or institutions which can and will operate at the intermediate level.

Quality assurance for radiation measurements at the users' level is the ultimate goal of the national measurement system. Through a variety of methods which are designed to test the users' capability to make field measurements with adequate accuracy and reliability, it can be determined whether the measurement assurance programs are operational, but they reach only a fraction of the universe of national users of radiation. These programs should also be operated by an intermediate level of organizations or institutions which, in turn, could be monitored by NBS to maintain overall quality of the system.

An important consideration in the implementation and operation of an effective measurement system is the crucial role of incentives. If there is no incentive for a radiation user to have his survey instrument calibrated, or to participate in a measurement assurance program, it is unlikely that he will do so. Indeed the current sporadic nature of users' utilization of these available services supports this contention. As a result, it is not unreasonable to question the degree to which public safety is assured. Although a minority of existing regulations promulgated by various levels of government make some attempt at requiring calibrations and traceability to national standards maintained by NBS, they are ineffective because the crucial terms are never defined in a meaningful way.

Recurrence of those measurement system deficiencies which were mentioned above in general terms will be recognized in the more specific following comments on particular types of radiation.

ULTRASONIC RADIATION

Medical applications of ultrasound are becoming increasingly important in diagnosis, therapy, and surgery. In these applications, high frequency sound waves are beamed through body tissue for therapeutic purposes, or to obtain information on body tissue from the modified waves, or to destroy a region of tissue. Even though the hazards associated with ultrasonic radiation at conservative power levels are generally conceded to be less than those associated with ionizing radiation, the hazards of ultrasound are the subject of continued research. An appropriate measurement basis for accurate dosimetry is a clear need. NBS has been strongly encouraged to assist ultrasonic applications through work on standards and measurement methods by equipment and transducer manufacturers, regulators, and consensus standards-writing bodies. The proliferation, in number and kind, of commercially produced medical ultrasonic equipment represents a large and rapidly growing pressure for precise and convenient methods for measuring the fields and charactistics of medical ultrasonic equipment.

This proliferation has resulted in a proposed safety performance standard for ultrasonic therapy and surgery devices since the FDA predicts that most of the 50,000 ultrasonic therapy machines in use produce an inappropriate amount of radiation. (1) Several standard practices documents have been drafted by consensus standards organizations. One of these requires traceability to NBS standards. In a recent survey in southern Florida, the Bureau of Radiological Health found inaccuracies as great as 100 percent in the instruments used by medical personnel. (2) To obtain the desired therapeutic, diagnostic or surgical effect without toxicity, the power, intensity, and field pattern of the radiation produced by ultrasonic instruments must be known. For specific applications there is often a need to determine additionally, for example, particle velocity, sound speed, absorption, attenuation, and acoustic impedance. Some commercially-produced or laboratory-produced instruments for the measurement of medical ultrasonic field quantities have been built. A very limited laboratory intercomparison has been carried out. Careful workers have attained uncertainties believed to be the ±5 to ±15 percent range for the field quantities of power, intensity, and pressure. Uncertainties in this range are not adequate for laboratories concerned with meeting and enforcing performance standards for ultrasonic equipment, yet ±5 percent uncertainties are difficult to achieve.

The maximum allowable power outputs for various types of medical ultrasonic equipment are being set by the Bureau of Radiological Health using the best available information on the power levels at which tissue damage might occur. Every user and manufacturer will need accurate measurements to insure that equipment is operating within the established limits; therefore measurement techniques and calibration services are essential. In research on tissue damage by ultrasonics, a basic standard is essential if damage levels are to correlate between researchers.

The character of the field radiated from a ultrasonic transducer controls the quality of the measurement and the interpretation of the measurement in diagnostic applications. The character of the field in therapeutic and diagnostic applications is the point of dosimetry concerns in ultrasonic applications. Yet there are no suitable, accepted methods for determining the field characteristics of transducers or of determining the effects of the electronic which drive them.

The NBS activities which most closely address this need area include the development of measurement methods for total radiated power versus frequency, and for time-averaged total power. These are quantities integrated over the field. Measurement services based on these techniques are available by special arrangement. In addition a computer-based technique is being developed to determine the relative value of point values of the field. The techniques being developed are for continuous wave excitation for the transducer radiating into water, an approximation for human tissue. The actual application, in most cases, uses a pulsed electrica lexcitation with the transducer radiating into biological material. It is clear that this actual application is different and much more complicated to measure or predict. Also, the limited techniques presently being developed are laboratory techniques. There is a clear, immediate need for even limited portable equipment for measuring ultrasonic radiation for use in hospitals. This need has been expressed by experts from several countries.

Due to the immaturity of the measurement methods and standards system and to the present level of NBS activity, no measurement assurance programs for ultrasonic dosimetry are planned in the near term. However, an intercomparison of power measurements methods piloted by NBS is underway. Owing to the recent and rapid rise in the incidence of exposure to ultrasonic radiation, particularly state and local groups have significant concern but little expertise or background in this area. Educational programs should be considered but are not in our near-term plans.

While the present measurement needs are great, there will be additional pressures in the near future. Single-element transducers are currently the most common applicators of ultrasonic energy. However a significant and increasing usage of multi-element phased arrays is occurring. More sophisticated and systems-oriented measurement methods will be required to characterize the fields produced by these devices. Generally, there is a rapid increase in the sophistication of the electronic parts of the ultrasonic radiation devices.

ELECTROMAGNETIC RADIATION (MICROWAVE AND RADIOFREQUENCY)

Research into the bioeffects of electromagnetic radiation has been predominantly based on the premise that the thermal effect is the primary concern and therefore measurements have been tailored to look for these results. Thus adequate measurement systems don't exist for non-thermal effects research. Bioeffects experiments require a far superior design if they are to isolate causes and effects both for thermal and non-thermal effects. Long-term, low-level exposure evaluation epidemiological studies to ascertain possible cumulative effects are drastically needed; reliable measurement techniques for such studies are almost non-existent. Assuming the research identifies a need for safety standards, then the living and working environments of the general populace must be measured and mapped (a task which has special measurement requirements as a function of the closeness and complexity of the emitting sources). This will clarify the dangers of using CB or land mobile radios, repairing television and radio towers, operating plywood driers and plastic molding machines, etc. The various levels and types of responsibilities for these activities need to be clearly enunciated. Later, as regulatory and safety compliance requirements are defined, mechanisms will be needed to define measurement support to effectively implement them.

Lower levels than those believed to be thermally bio-hazardous can be severely disruptive to electronic controls upon which human life may rely, such as heart pacemakers, electronic braking controls, and kidney dialysis machines.

On a national basis, the radiation measurement system is not well defined in that researchers of bio-effects are in general not locked into an absolute base which would relate all experimental results to a common foundation. Part of the reason for this weakness is the lack of facilities and resources at NBS and the need for a deliberate program designed to assist researchers, and to educate them in the effective use of electromagnetic measurements. Measurement methods and standards do not exist or are inadequate for measuring complex electromagnetic fields such as those generated by pulsed signals, impulsive signals, and multiple-source environments.

We have a reasonable national capability for measuring average power far from emitting sources and a very limited capability for measuring close to emitting sources. To measure complex signals will require that new instrumentation be developed, together with measurement standards and ways to disseminate this capability through institutions, States, and Federal agencies. We have defined an NBS program that is addressing these needs, albeit with minimal funding. Presently, NBS research is in progress to develop measurement instruments for pulsed fields and for impulsive fields. We are also engaged in developing an anechoic chamber and TEM cells as means of developing standard measurement fields for the evaluation and calibration of instruments. Remote or unmanned monitoring instruments are also being investigated. A special temperature probe for use by bio-researchers in this field is being developed.

The current national proliferation of electromagnetic sources is significant. Examples are microwave ovens, mobile radios, industriial applications of radiofrequency and microwave heating and curing equipment, and satellite communications. The complexity of the environment is increasing and measurement of it will be more difficult as we attempt to understand its impact on non-thermal bioeffects. This will require the development of measurement standards and instrumentation capable of assessing environmental complexity. It will also require the development of simulators that can reconstruct these complex environments for bio-effects research, and that can vary the degree of complexity for determination of non-thermal effects that may be cause.

As vehicles, cars, and airplanes are fabricated out of non-metallic substances for weight savings, passengers will be exposed to more radiation from radars and natural sources such as lightning. The needs for regular environmental monitoring will be increased to assure the safety of humans from direct and indirect effects; such monitoring will have to assess the quality of the environment for waveforms, power, and possibly polarization as a function of frequency. This information will be necessary for researching the non-thermal effects on biological subjects.

Special marginal localized environments may have to be regulated and monitored frequently by States for public safety such as health conditions in restaurants are monitored. The States may need to monitor compliance with regulations by industries and users to protect consumers as weights and measures are monitored today; for example, the impulsive EM radiation from internal combustion engines which could have long-term non-thermal dangerous effects when metal bodies no longer exist on cars.

ULTRAVIOLET RADIATION

The Nation's need for increased accuracy in radiometric measurements and calibrations is being urgently felt in a variety of fields important to the economy, to the environment, and to public health. For example, the national program to predict the future world climate is in large measure dependent for its success on accurate measurement of solar radiation, both in space and on the surface of the earth. A recent interagency workshop laid out the criteria for the radiation measurements needed. That group set as minimum requirements an accuracy level of 0.1 percent for total solar radiation and 1 percent for spectral irradiance measurements from about 4 microns in the infrared to 120 nm in the ultraviolet. These accuracy levels must be maintained on the same absolute scale for a period of 22 or more years. Both requirements are well beyond the present capability of any laboratory, including NBS. The workshop has designated NBS as the only laboratory capable of developing the requisite level of accuracy, and in their report NBS was given the responsibility of developing and disseminating the measurement capability. (3) NBS must develop a technology for these more accurate measurements and must transfer it to space and field instruments.

Urgent new needs specifically for accurate UV radiometry have been created by the recent recognition that solar and artificial UV radiation pose a severe threat to both the environment and to public safety. For example, accurate monitoring of the UV transmission characteristics of the earth's atmosphere is an important long-term national problem being faced by several Federal agencies (NASA, NOAA, EPA). The inadequacy of the present national measurement system for UV radiation has interfered with the accuracy of the existing data and frustrated attempts to detect long-term trends. The climatological and biological hazards associated with possible changes in the UV transmission have far-reaching effects that include a potential increase in the incidence of skin cancer and adverse changes in agricultural production that would diminish the world's food supply. The Secretary of Agriculture recently identified ozone depletion through the use of nitrogen fertilizers, which would lead to an increase in UV transmission of the atmosphere, as one of the most important current research problems facing the nation. (4)

Also, radiation of all types is being increasingly used in our modern technological society for public benefit, while at the same time there is increasing public concern, and resulting regulatory legislation that these benefits of radiation be achieved without undue adverse impact on the public. For example, potential hazards exist for exposure to artificial UV radiation due to the rapidly increasing use of UV-rich sources in industrial processing, artificial illumination, and medical therapy.

More than 40 occupations have been identified by OSHA and NIOSH as presenting significant health hazards because of UV exposure. (5) BRH is currently developing performance standards for the UV radiation devices involved. Calibration standards from NBS will be necessary to make compliance with regulations possible in tihs area.

The NBS program plan places emphasis on the development of improved calibrations, the development of new national standards, and a systematized dissemination mechanism to transfer the radiation measurement technology to to users. The ultimate beneficiaries of the program will be the entire nation in terms of understanding future climatological trends, the general public in terms of safety from increasing levels of hazardous UV radiation, and the consuming public in terms of effective long-range plans for agricultural products.

As a short-term program, supported partially under a contract with EPA, our capabilities for source-based radiometry are being used to calibrate near-ultraviolet sources and to calibrate a radiometer which is used for studies of the biological effects of ultraviolet radiation. Our plasma spectroscopy group is developing the argon plasma arc as a portable standard for ultraviolet radiation. Calibrations of detectors and spectrometers in the far ultraviolet are being made with the NBS synchrotron ultraviolet radiation facility. New techniques based on electrically calibrated detectors and electro-optic technology are being used to calibrate silicon detectors in the near ultraviolet.

Substantially increased funding will be necessary to expand the current programs and to develop the necessary techniques and technology that will meet the urgent new requirements for transferring UV measurement capability with the needed accuracy to the national measurement system over the long term.

New ultraviolet radiation measurements milestones have been developed by NBS with extensive consultation with the Interagency Task Force on Inadvertent Modification of the Stratosphere (IMOS), the committee for Biological and Climatic Effects Research Program (BACER) of the Environmental Protection Agency, and the Council on Radiation Measurements (CORM), a group with substantial representation from the lighting and electro-optic industries. Several workshops have been held and attended to help in determining the most important goals.

IONIZING RADIATION

Although the national program for control of ionizing radiation is highly fragmented, with many responsibilities assigned to many agencies at the federal, state, and local level, the authority for enforcing compliance with the established maximum permissible levels of radiation to which the public may be exposed can only be made on the basis of measurements. For effective and equitable enforcement of regulations, these measurements must be made with sufficient accuracy and reliability. Uniformity of measurements is of primary importance for conformity between the regulator and regulatee. Thus it is essential that all field measurements have meaningful traceability to the national reference standards maintained by NBS, through a well-defined system of calibrations or measurement assurance. Unfortunately an adequate national system does not exist at this time, and most of these instruments at the user level have not been adequately calibrated. In addition, present measurement assurance programs have limited effectiveness and represent only piecemeal attempts at solving the national problem.

In recognition of this situation, NBS requested increased funding for services to state radiation control programs. In fiscal year 1975, limited funds were granted with the stipulation that initial efforts be directed toward a survey of measurement needs and capabilities in state programs. The survey was begun in February 1975 and was essentially completed in the summer of 1976. A simultaneous study was conducted by a task force of the Conference of Radiation Control Program Directors to obtain an analysis of the situation from the state perspective. Summaries of the NBS and state studies are available and copies can be provided to your Committee if desired. (6,7)

The conclusions reached by both studies were generally similar, particularly with regard to identification of major problems. The ten recommendations resulting from the task force study follow:

"1. There is a need for more direct NBS assistance to the states in the areas of physical standards and measurement systems for radioactive materials and ionizing radiation. In particular NBS should develop a mobile calibration laboratory to assist the states in both quality assurance and training.

2. NBS should provide more standard reference sources directly to the states at little or no cost.

3. NBS should review and approve all federal guidelines, standards, and regulations which require radiation measurements prior to the promulgation of such guidelines, standards, and regulations to assure that such radiation measurements are both technically feasible and practically attainable.

4. NBS should coordinate the development of model sampling procedures, chemical separation procedures, and analytical measurement methods for a variety of environmental radiocontaminants which could be used by all state, federal, and private laboratories to assure consistency in the quality of measurements.

5. NBS in cooperation with EPA should be designated as the federal agency responsible for coordinating efforts among the federal and state agencies to immediately develop a uniform data reporting system so that present environmental data which are being generated throughout the country can be utilized and evaluated in terms of possible population exposures.

6. NBS should design a model calibration facility and recommend procedures for calibration of field ionizing radiation survey instruments and monitoring systems.

7. There is a need for additional training for all State personnel involved in ionizing radiation measurements. Training programs should be sponsored and supported by all Federal agencies involved in ionizing radiation measurements. It is recommended that the Conference of Radiation Control Program Directors establish a Task Force on Training which would, as part of their efforts, coordinate the training activities sponsored by Federal agencies.

8. NBS should begin to work with specific states to resolve specific measurement problems which could be applicable to the remaining states. Such areas may include the design and operation of a state calibration facility, calibration of specific instruments for specific types of measurement problems, etc.

9. The present Environmental Protection Agency environmental radioactivity laboratory intercomparison studies program provides a cross-check on individual laboratories. That program has been very successful in identifying specific problems. However, there is presently no follow-up program to provide assistance to those laboratories which the cross-check program identifies as having such problems. The Task Force recommends that the Environmental Protection Agency, the Nuclear Regulatory Commission, the Energy Research and Development Administration, and the National Bureau of Standards cooperate in resolving this issue.

10. The Task Force was only able to scratch the surface of the problems. It is believed that a more in-depth analysis would be appropriate and may alter the above recommendations. Therefore, as a final recommendation, the National Bureau of Standards should continue to sponsor the Task Force on Radiation Measurements in a manner suitable to both the National Bureau of Standards and the Conference of Radiation Control Program Directors.

Perception of state program needs from the NBS viewpoint must be conditioned by the boundaries imposed on NBS by its legislated authority. Thus the strongest consideration must be given to those needs concerned directly with standards, their dissemination, and measurement assurance activtities. In addition, the development of standard practices must be given strong consideration.

Development of an NBS program which is responsive to state needs is being guided by the limits of NBS functions, as well as the restrictions imposed by limited resources. The latter will not allow us to develop a comprehensive program, but will enable the initiation of a limited number of pilot programs. From these limited efforts we hope to develop a foundation for future expansion.

Perhaps the clearest need discovered in the study relates to calibration of survey instruments, particularly those used for measurement of x and gamma radiation. This represents an area of major concern to state programs. Consequently we have begun a pilot program with the State of Illinois to establish an in-house calibration capability in that state program. Originally the pilot effort will concentrate on development of a calibration facility in the 50 to 120 kilovolt range, with exposures from 100 mR to 1.5 R. This is the area of interest for enforcing the Illinois regulations relating to maximum exposures of patients during x-ray diagnostic procedures. Essentially all the other states also have an interest in this area and the experience gained through this pilot program should have wide application. In addition, the Illinois calibration facility will be available to serve the needs of the surrounding states as a regional laboratory. This will be an interesting test of the concept of having a state laboratory serve as a regional facility.

In the area of laboratory analysis of environmental samples, we have begun to coordinate a project which has as its purpose to "establish more standardization in data reporting conventions including the definitions of detection limits and the treatment of results at or below these limits." This activity is consistent with the recommendations of the Task Force report. In June the first meeting was held of the subcommittee formed to address the problem. At this time, the subcommittee membership includes representatives of the states, a utility, a contractor, NRC, ERDA, HASL, EPA, HSL (Health Services Laboratory in Idaho Falls), and NBS. Subtasks have been assigned to the members, on the specific subjects of confidence level, random and systematic errors, units, detection limits, and significant figures. Assuming a consensus can be achieved, the recommendations of this subcommittee will be of value to all state programs. This project is one of nine which are included in the overall program of the Steering Committee on Upgrading the Quality and Usability of Environmental Radiation Data, sponsored by the Health Physics Society.

A third pilot program is concerned with field measurements of low-level environmental radiation. In response to a request from the State of Florida, we have begun a project which will lead to the construction of a distributed calibration source for instruments used to measure gamma levels in the vicinity of 10 μR/hr. This particular level is of interest because of the current EPA interim recommendations for gamma exposure levels at new structure sites on Florida phosphate lands. A distributed calibration source is desirable because large errors may result if a point source is used to calibrate istruments which measure distributed where phosphate or uranium mine tailings present present problems.

Other pilot programs will be added if possible within our resource limitations. Needs in state programs will continue to be studied in greater detail, and adjustments in NBS activities may be made as the result of further studies. Anticipated future needs will occur from increasing use of neutron and high-energy x rays in medical and industrial applications.

There is an obvious common theme in the above brief descriptions of the situation regarding the four selected types of radiation. There is a proliferation of radiation sources which results in increasing probability of public hazard; some of the hazards are well defined, some are not; if they are defined, regulations are issued at federal, state, and local levels; if the hazards are not well defined, research is being done to determine better definition; reliable measurements are essential to the definition of hazards and to enforce regulations; all levels of regulators and regulatees must be on the same measurement basis; that basis must be developed and disseminated by NBS; intermediate levels must serve as dissemination mechanisms; limited resources are a problem at all levels; adequate incentives are lacking in most cases; the public demands and deserves assurance of high-quality measurements at the user level. This sketches a rather difficult national problem which must receive more attention.

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3. Draft report of the Workshop on Monitoring the Solar Constant and Solar Ultraviolet, sponsored by the Air Resources Laboratory of NOAA and the Cooperative Institute for Research in Environmental Sciences, Estes Park, Colorado, August 8–12, 1977.

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5. Gafafer, W. M., "Occupational Disease—A Guide to Their Recognition," Publication 1097, U.S. Dept. of Health, Education, and Welfare, Public Health Service, 1966, pp. 260–61.
6. Final Report, Task Force on Radiation Measurements, Conference of Radiation Control Program Directors, February 1977. (Thomas M. Gerusky, Chairman).
7. Eisenhower, E. H., "Report of NBS Survey of State Measurement Needs," 9th Annual National Conference on Radiation Control, June 19–23, 1977, Seattle, Washington. Paper to be published in the Proceedings of the Conference.

COMMITTEE QUESTIONS TO DARPA

Question 1. What were the reasons for classifying the research project known as "Project Pandora"?

Question 2. What was the cost of Project Pandora? What were the costs of the Walter Reed facilities and of the research projects undertaken within the facility?

Question 3. What has happened to raw data amassed during Project Pandora?

Question 4. In testimony before this Committee witnesses from the Department of Defense were unable to tell us whether or not the relevant data from Project Pandora has been destroyed or whether or not it still exists. If the data still exists, is it still classified? If the data does not exist, what happened to it?

Question 5. The witnesses testifying at the hearing tentatively guessed that the data were destroyed. If the data were destroyed, what were the reasons for its destruction? How often are documents containing data such as those involved in Project Pandora routinely destroyed? Please describe procedures for such routine destruction.

Question 6. Please provide the Committee a description of the project currently being undertaken at the Walter Reed facilities which were originally built for Project Pandora. Dr. Herbert Pollack, in his testimony before the Committee, stated that the Water Reed facilities were currently being rebuilt. Why are these facilities being rebuilt? At what cost?

Question 7. Are there now, or have there ever been, research projects on the biological or behavioral effects of non-ionizing radiation, such as Project Pandora, which have been classified?

Question 8. Does your agency see the need for such research ever again to be classified?

Question 9. Are there now, or have there ever been, research projects classified or unclassified conducted under the auspices of the Department of Defense which would have probed possibilities of utilizing microwave radiation as a form of what is popularly known as "mind control"?

Question 10. Several of the witnesses alluded to "novel utilization of the spectrum". Do you foresee the development, either by our own forces or by adversary forces, of weapons using microwaves and actively being directed toward altering nervous system function or behavior?

Question 11. Is the United States involved in developing any directed energy microwave weapons?

Question 12. Is there any evidence that Eastern Block research on microwaves is being actively directed toward altering nervous system functions from a weapons point of view?

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY,
Arlington, Va., September 15, 1977.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce, Science and Transportation, Washington, D.C.

DEAR MR. CHAIRMAN: Reference is made to your letter dated 12 August asking a number of questions concerning Project Pandora.

In response to these questions, the following information is furnished:

1. Project Pandora was classified in the direction of the Department of State and the United States Intelligence Board because of the sensitivity of the radiation problem of the United States Embassy in Moscow at that time.

2. The total cost of Project Pandora was $4,615,000. A detailed breakout of the costs of the Walter Reed facilities and of the projects undertaken within the facility is not available.

3. All the raw data of Project Pandora was amassed by the technical researchers with only technical progress reports of what disposition was made of the raw data.

4. This agency has available a number of technical documents identified as "Minutes of Pandora Meetings" as well as several technical reports. These documents have been declassified.

5. This agency has no knowledge as to whether the data collected at Walter Reed were destroyed and, if so, the reasons for its destruction. Documents containing research, development, test and evaluation information or data are handled by this agency in accordance with the requirements of the Federal Records Act of 1950, Public Law 754, 81st Congress, as implemented by Department of Defense Instructions.

6. Project Pandora was terminated by DARPA in March 1970 and all assets were transferred to Walter Reed Army Institute for Research (WRAIR) for disposition. Since that time, there has been no DARPA interest in the work being carried on at WRAIR and consequently we would have no knowledge as to the project currently being undertaken, or that the facilities were being rebuilt, the reasons for rebuilding and the cost.

7. With the exception of Project Pandora, this agency has not sponsored any research projects, either classified or unclassified, on the biological or behavioral effects of non ionizing radiation.

8. As stated earlier, classification of Project Pandora was a foreign relation rather than a national security matter. While it is likely that the technical aspect of such research efforts would be unclassified, the determination of a security classification must consider the potential application of the research and its effect on our national security.

9. This agency is not aware of any research projects, classified or unclassified, conducted under the auspices of the Defense Department, now on-going or in the past, which would have probed possibilities of utilizing microwave radiation as a form of what is popularly known as "mind control."

10. We do not foresee the development, by DARPA, of weapons using microwaves and actively being directed toward altering nervous system function or behavior. Neither are we aware of any of our own forces or possible adversary forces developing such weapons.

11. Although this agency is not presently involved in developing any directed energy microwave weapons, we do know that the United States, in the past, has conducted research and exploratory development on the generation of high power microwave radiation and its effects on electronic components.

12. This agency has no evidence that Eastern Block research on microwaves is being actively directed toward altering nervous system functions from a weapons point of view.

Sincerely,

George H. Heilmeier, *Director.*

Unclassified Documents Pertaining to Project Pandora

Department of the Navy,
Office of the Assistant Secretary,
(Research and Development),
Washington, D.C., December 20, 1976.

Mr. Fred A. Koether,
Defense Advanced Research Projects Agency, Arlington, Va.

Dear Fred, I am enclosing copies of all the papers I collected which were directly or indirectly part of Project Pandora. I wanted to particularly note that the Bernice Cohen paper has, in recent times, been refuted by the author's further investigations. There is no evidence in the final analysis of a correlation between radar operators and Mongoloidism.

There are other papers, but not included in this package. One that comes to mind which should probably be declassified, if not already, is a paper prepared by Janet Healer at Allied Research on a computer analysis of Soviet papers in the field, circa 1966. Also a paper by Janet Healer, myself and Herb Pollack, printed by Allied Research and submitted probably around 1970 has a pretty thorough review of Soviet literature to that time. It has been widely circulated but never officially released by ARPA.

I believe the ARPA committee report and the APL document describing the facility represent the most cogent papers written on the basic project. As you may know, when I searched for this information, I found the data books had been destroyed. There may exist one or two of Dick Cesaro's flash bulletins at the Top Secret level in the CIA archieves, but as an IDA analysis shows, these were meaningless. Various reports exist at the classified level of the actual measurements of the signal in Moscow. I don't believe these are germane, but I will be happy to give you more information if you need it.

By the way, I have included a letter to President Ford and a response signed by George Heilmeier in case you haven't run across it.

Sincerely,

SAMUEL KOSLOV,
Special Assistant for Science.

February 5, 1976.

MR. DON JOHNSON,
Oakland, Calif.

DEAR MR. JOHNSON: On behalf of President Ford, I am replying to your Mailgram of January 22nd bringing Project Pandora to his attention. This project, which has not been active for several years now, was concerned with the biological effects of microwaves and investigated the adequacy of established safety levels for normal working exposure to radio frequency radiation.

It had been suggested (wrongly, as it turned out) that new biological effects of microwave exposure might be possible, and Project Pandora was designed to test this conjecture. When it became apparent that established U.S. standards for radiation are adequate and that no new effects could be observed, the project was terminated. The Pandora experiements were never directed at the use of microwaves as a surveillance tool nor in a weapon concept. Weaponization is not feasible, and the only present surveillance uses of microwaves are in connection with rather short range radars for battlefield applications such as locating enemy vehicles at night or in fog or haze.

Sincerely,

GEORGE H. HEILMEIER, *Director.*

TELEGRAM

OAKLAND, CALIF., *January 26, 1976.*

PRESIDENT GERALD FORD,
Care RON NESSEN,
White House,
Washington, D.C.

While your staff is considering revamping the intelligence community perhaps you may want to look into the following. I have been told by people that have done research with the Department of Defense in the area of microwave that a secret project Pandora or another security program started during the Kennedy Administration involves the use of advanced microwave surveilance type of instrumentation. It is a joint Army/Navy activity.

Sincerely,

DON JOHNSON.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY,
Arlington, Va., May 20, 1976.

DR. SAMUEL KOSLOV,
Special Assistant for Science,
ASN (R. & D.),
The Pentagon.

DEAR SAM: Enclosed are copies of everything available which I believe to be useful Pandora documentation. The sources for these are the retired ARPA file and the file which IDA recently transferred here and which I have now added to the ARPA material. I plan to have the ARPA records returned to the Federal Records Center on 1 June; if you need to look further, please let me know before then. What you would see, however, is a callection of administrative paper, quarterly technical reports which are subsumed in the enclosed stuff, and a few pieces of correspondence. None of this has useful technical content so far as I can tell. Apparently, such major reports as may have been produced reposed at WRAIR and have been destroyed.

Please use the enclosed papers as you see fit, including transferring them to the Department of State if that is the logical repository. I doubt that the Secret material is worth the effort to declassify, but will leave that to your judgment. The caveats "Advanced Sensors—Limited Distribution" market d on some of the IDA material of course no longer apply; so far as I know, they never had any legal force anyway.

Again, good luck. I hope this helps.

Cordially,

F. W. NIEDENFUHR,
Director, Technology Assessments.

Enclosure.

MINUTES OF PANDORA MEETING OF JANUARY 12, 1970

Attendees.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. James N. Brown, Dr. H. Allen Ecker, Gen. Carl Hughes, Dr. Joseph Kubis, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack, Secretary, and Dr. Lawrence Sher.

Walter Reed Army Institute of Research: Col. Joseph V. Brady, Dr. Thomas W. Frazier, Mr. T. Daryl Hawkins, Col. Merrill C. Johnson, Maj. James T. McIlwain, and Col. William H. Meroney.

Mr. Albert Rubenstein, ARPA.

Absent.—Mr. Richard S. Cesaro, ARPA. Dr. John J. Collins, (CNO), USN. Mr. H. Mark Grove, Wright-Patterson AFB. Mr. Harris B. Stone, (CNO), USN.

I. BACKGROUND OF THIS REPORT (U)

(S) Certain events presumed to be threatening to the national interest served as a basis for ARPA's support of project Pandora. WRAIR was given funds and responsibility in early 1965 for research to evaluate the threat, since it appeared to have strong behavioral and biomedical implications. The WRAIR charter included in-house and extramural contract activities. The intramural program was largely, but not exclusively, directed toward evaluating behavorial end points using the WRAIR (special) signal on primates. The extramural support was largely biomedical.

(S) Preliminary analyses of in-house results presented by Dr. Joseph Sharp of WRAIR in 1967 encouraged the belief that the special signal altered primate behavior. Moreover, preliminary extramural cytogenetic and histological studies of the brain suggested that comparable energies were damaging to tissue.

(S) The Pandora Scientific Advisory Committee (SAC) was appointed in 1968 to provide advice for the development of the research program. The initial presentation of the in-house WRAIR data to the SAC consisted of the citation of selected cases and samples of the raw data. Requests were made by SAC for a fuller presentation of the material, since a choice of future strategies and methodology depended on the validity of the reported findings. By this time Dr. Sharp had left the Project, and an effort to be responsive to the Committee was made by Dr. James McIlwain of WRAIR. Dr. McIlwain's analyses suggested, in contrast to the initial analyses, that if the signal had an effect on behavior, it was so modest as to be obscured by effects of experimental, procedural variations, which were a result of the exploratory character of the early experimental program. Furthermore, continued extramural cytogenetic studies did not confirm the earlier reports of changes in tissue exposed to the signal.

(S) The apparent differences of initial and later experimental findings are significant from a research management point of view and should be assessed within the context of the following concurrent events:

1. The realization that research in this field is comparatively costly in equipment and effort and that large sums of money have already been allocated to equip a new laboratory at WRAIR and at Johns Hopkins University. Further, management of this highly technical facility and the experimental program requires high level behavioral, biomedical, and engineering capability.

2. Definitive research in this area will also require work with human subjects, and ethical procedures for working with humans may conflict with security needs.

3. The prescription against DOD support of basic research, unless it can be shown to have relevance to national defense and the recent general edrying up of research funds generally.

(S) In view of these considerations, research programming decisions are particularly dependent on whether the early WRAIR reports (to the effect that the signal does affect behavior) are correct or whether the later analyses refuting these reports are more credible. Because of his special competencies in statistics and experimental design. Dr. Joseph Kubis, a member of SAO, was asked to do an intensive evaluation of the procedures, the protocols, the data, and the assumptions on which subsequent interpretations of the data were made by Dr. Sharp and Dr. McIlwain.

(U) What follows in Section II is a summary and elaboration of Dr. Kubis' report agreed upon and accepted by members of the Scientific Advisory Committee.

II. THE COMMITTEE'S RESUME OF THE KUBIS REPORT (U)

(S) The earlier demonstration that the signal has an effect on primate behavior relates mainly to the procedures Dr. Sharp applied. To make the allegation credible, it should be demonstrated that a statistically significant rather than a chance difference exists between experimental and control conditions. Dr. Sharp s treatment of the experimental and control conditions can account for some part of the difference in effects. However, for understandable reasons, to be elaborated below, Dr. Sharp's evaluation did not adequately demonstrate the difference defined above.

(S) Dr. McIlwain's treatment of the data and associated experimental procedures was detailed and critical. However, if the error of obscuring an effect which may be there is to be avoided, certain additional statistical treatments are suggested. Moreover, it is SAC's judgment that any signal effects that can be teased out by further statistical treatment will, at best, be minor in comparison with effects generated by a host of procedural manipulations, some of which are intentional and some unintentional, which is characteristic of most exploratory or pilot studies.

(U) The differences between Dr. Sharp's and Dr. McIlwain's analyses are summarized below under the following headings:

(A) Assumptions and Criteria; (B) Contamination of the Control Condition; (C) Contamination of the Experimental Condition and (D) Statistical Treatment Problems.

A. Assumptions and Criteria (U)

(S) Both Drs. Sharp and McIlwain assumed that the effects (if any) of the signal on performance would be deleterious. Dr. Sharp was looking for performance impairment on any subject and in any temporal form, i.e., sudden, progressive, et cetera. This approach is advisable for an exploratory effort. However, with small numbers of experiments, subjects, and varied procedures, the dragnet approach makes the investigator vulnerable to confusing a random variation with a significant one.

(S) Dr. McIlwain assumed in most of his analyses that the effects are cumulative and that performance could be worse in the second half of the exposure period than in the first half. This is a reasonable assumption. but the data do not support this asumption of how the signal might function. The signal might indeed affect behavior and animals selectively, but if it does, then stable baselines are essential for such effects to be demonstrable. The lack of stability of the baselines is discussed later.

B. Contamination of the Control Conditions (U)

(U) Dr. Sharp's and Dr. McIlwain's approaches differed on the nature of the control conditions employed in these experiments. Dr. Sharp used baseline data obtained from all sections of the extensive experimental protocols so long as they were "after training and before exposure." Dr. McIlwain assumed that with so many changes in experimental procedures, no adequate baseline could be established. As a result his analyses were confined only to the experimental condition. As mentioned before, these analyses rested on the assumption of a cumulative effect.

(U) When changes in situational conditions produce pronounced nonexperimental effects, it is rather clear that baselines following such changes become heterogeneous. Lumping them together does not provide an adequate base for evaluating specific experimental effects. Thus, Dr. Sharp's findings cannot be entertained with confidence unless an analysis of available protocols is made to show that there are sufficient data points to provide an adequate baseline.

(S) What is critical, moreover, is the unknown effect on baselines produced by the numerous changes in the experimental environment (icebox vs. anechoic chamber, night vs. day, alone vs. with other animals, et cetera). It is a problem to determine when that baseline has reached asymptote after it has been sharply shifted by the changes in the experimental environment. When these shifts in baseline are much more pronounced than any changes by the experimental signal, one is inclined to view the effect of the signal itself either as "subtle" or of doubtful, practical significance.

(U) In addition, the cyclical nature of both the control and experimental conditions (which is necessary when working with a single animal who serves as his own control) can be self-defeating if the experimental condition produces a cumulative and permanent effect. Under such conditions the control (absence of signal) period becomes contaminated by the lingering effect of the previous experimental condition, thus making subsequent comparisons between the two conditions nondiscriminative.

(U) Under the conditions of these experiments the problem of baselines is beset with theoretical difficulties. However, the possibility of their use can be evaluated on the basis of the data available for each specific change in environmental condition.

C. Contamination of the Experimental Conditions (U)

(S) Neither Dr. Sharp nor Dr. McIlwain regarded the experimental design itself as a significantly limiting factor in the analyses of the data. Dr. McIlwani, for example, divided the experimental condition into equal time segments and tested for differences in effect between the first and second halves. There is, however, a possibility of contamination of the experimental condition in terms of its interaction with the changes in the environment under which the testing was done. Unless the interaction effect is explicitly planned for and evaluated, the experimental condition may be producing effects magnified under some conditions and reversed under other conditions so that a "deleterious" effect could be inferred in the first situation and a "beneficial" effect in the second. Such paradoxical results may be the outcome of continued analyses where the possible interaction effect has not been isolated and explained.

(U) Both control and experimental conditions could be contaminated by the presence or absence of a "weekend effect," when a significant change in the level of the background noise occurs in the laboratory. The data were not analyzed to determine whether this condition affected the experimental and control conditions differently. Similarly, equipment malfunction disrupted performance during control and experimental conditions, but no statistical analyses were provided to determine whether this was a differentially significant constraint.

D. Statistical Treatment Problems (U)

(U) Dr. Sharp's and Dr. McIlwain's approach each provided some statistical analysis of the data. Dr. McIlwain's statistical treatment was more extensive and utilized some relatively simple but effective nonparametric procedures.

(S) Dr. McIlwain seems to have shown that there are no consistent differences between the first half and the second half of the exposure period. According to his assumption that an incremental increase in effect should be expected, the results are negative. The possibility that there was an initial effect which persisted at about the same level during the exposure period is not to be ruled out by Dr. McIlwain's analysis.

(S) There are selection and computing problems associated with Dr. Sharp's presentations. On the basis of these difficulties it cannot be asserted that Dr. Sharp had established the existence of an effect due to the experimental signal. No written report has been produced by Dr. McIlwain due to the pressure of time. The conclusions herein expressed are based on limited visual examination of notebooks containing such data, charts, and graphs.

(S) From the overview available to SAC of both analytical approaches, SAC has concluded, regarding the experiments considered to date, that if there is an effect of the signal utilized to date on behavior and/or bio-medical functions, it is too subtle or insignificant to be evident.

III. SUMMARY AND RECOMMENDATIONS (U)

(S) A. The research effort mounted by WRAIR to date has been exploratory and consequently diffusely programmed. No definitive answer to the question of whether the original signal has any effect on the performance of operantly-conditioned monkeys has been provided to date. However, since no clear and strong effects have become apparent with the WRAIR signal, the findings thus far can be regarded as negative. Any plan to renew an animal (primate) study should be carefully reviewed and critically evaluated by an expert scientific and research management body.

(S) B. The WRAIR signal is composed of selected components of the original complex signal. The negative results may be considered as due to the fact that inappropriate aspects of the signal were replicated. If additional major research were to be mounted regarding Pandora, attention should be given to the original signal.

(S) C. Consideration has been given to the matter of planned human experiments using the WRAIR facility and signal. SAC concludes that, based upon existing information, there is no evidence that [no] any permanent, deleterious effects are to be expected. Also, it appears that security and ethnical questions have been resolved. However, SAC also concludes that it is likely the results of human experiments would be indistinct in the same way as those of the animal experiments. Thus, additional expensive and time-consuming human experiments might raise the same questions as raised by the animal experts, including the question of the appropriateness of the selected experimental signal. There are, however, differences between the human and primate, for example, the size and shape of the skull. Furthermore, it should be recalled that little investigation was performed in the animal experiments regarding biochemical and clinical effects. The animal experimental end points were essentially behavioral.

(S) D. A decision about whether this field as a whole warrants a high priority cannot be made in isolation from a knowledge of other problems involving threats to the national interest. SAC has not been privy to other efforts. It may be assumed that continued medical follow-up of personnel exposed to the original signal has been developed, but no details on such a follow-up have been provided. There do seem to be certain investigations which could be performed that might shed further light on possible effects of the original signal. If, however, such work is not being done, we believe it useful to support a study to consider such activities. For example, individuals assigned to selected posts are examined before they leave and at six-month intervals. The examination should include comprehensive biochemical, medical, biomedical, and psychometric performance tests that could plausibly detect any changes. A control group would be essential. If on the basis of such a systematic study significant differences appeared, we would recommend the focal research cited above be given a high priority.

Respectfully submitted by Lysle Peterson, Chairman.

INSTITUTE FOR DEFENSE ANALYSES,
Arlington, Va., March 31, 1970.

MR. RICHARD S. CESARO,
OSD/ARPA/Advanced Sensors, Pentagon,
Washington, D.C.

DEAR MR. CESARO: The minutes of the Pandora meeting of January 12, 1970, contain a grammatical error of a double negative on page 6, paragraph C, line 2.

The sentence should read, "SAC concludes that, based upon existing information, there is no evidence that any permanent, deleterious effects are to be expected" rather than "SAC concludes that, based upon existing information, there is no evidence that no permanent, deleterious effects are to be expected."

Yours truly,

MARILYN CHANDA,
Secretary to Dr. H. Pollack.

Date: January 14, 1969. Memorandum to: Mr. R. S. Cesaro, ARPA. From: IDA Review Panel. Subject: Flash Report on Pandora/Bizarre Briefing (S).

(S) In response to a request from Advanced Research Projects Agency (ARPA), a special panel was convened by the Institute for Defense Analyses (IDA) to review the research techniques, results to-date, and to make recommendations for the future of the Pandora/Bizarre program.

(S) The IDA Panel personnel were as follows:

1. Lysle H. Peterson, M.D., (Chairman) Univ. of Pennsylvania.
2. Joseph E. Barmack, PhD, C.C.N.Y.
3. Joseph F. Kubis, PhD, Fordham University, N.Y.
4. BG Frederic J. Hughes, M.C., Walter Reed Gen. Hospital.
5. Herbert Pollack, M.D., Institute for Defense Analyses.

(S) Observers present were:

1. Richard S. Cesaro, OSD/ARPA/AS.
2. James P. Deck, Colonel, Wright Patterson AFB, AFAL.
3. Daniel J. Sullivan, OSD/ARPA/AS.

(S) The briefings were presented by:

Col. J. Brady, M.S.C.—WRAIR.
Maj. J. Sharp, M.S.C.—WRAIR.
Capt. McIlwain, M.C.—WRAIR.
Mark Grove, AF Avionics Lab—WPAFB.

(S) The panel met at 0900 on Friday, December 20, 1968, in the Forest Glen Annex of the Walter Reed Army Hospital. All persons present who had not done so previously signed the Pandora/Bizarre clearance forms. Briefings and an inspection of the physical plant lasted until 1230. The panel and the briefing team drove to the Institute for Defense Analyses where they reconvened at 1300 hours. Further discussions were carried on until 1500 hours, when the panel thanked the briefing team and went into executive session.

(S) The terms of reference for the review panel as presented by Mr. Cesaro called for an initial flash report based upon the briefings of the day. Mr. Cesaro indicated that he expected the panel to operate on a continuing basis until the project was completed. It is expected that the panel would be enlarged in the near future as soon as clearance procedures permitted.

(S) The flash report was to be the response to the following questions posed by Mr. Cesaro:

1. Does the panel consider the research procedures reported at this briefing scientifically sound and capable of supplying the data required to satisfy the stated objectives?
2. Does the evidence presented support the stated deductions or conclusions?
3. What future plans and procedures should be adopted in view of the findings to-date?
4. Does the panel consider it necessary to develop a "real time" data processing technique to facilitate the identification of those components of the "synthetic signal" which are responsible for the observed biological effects?
5. Does the panel wish to express an opinion as to the mechanism of the action of the electromagnetic radiation on the intact animal?

(S) The panel was unanimous in its opinion that the use of multischedule programs for operantly conditioned monkeys was a sound and acceptable technique to assess degradation or acceleration of work patterns. That the monkeys exposed to the specific "synthetic Moscow signal" in field strengths from 1 mw/cm^2 up to 4.6 mw/cm^2 showed degradation of work performance after 10-hours-a-day exposure for from 11 days to 21 days. This degradation in performance may be regarded as a "vigilance function degradation." The effects appear to be grossly functionally reversible. There is some evidence that repeated series of exposures sensitizes the animal and shortens the latent period before signs of vigilance degradation appear.

(8) The WRAIR investigators attempted to develop techniques with more rapid response times in the hopes of being able to facilitate the identification of the elements of the synthetic signal responsible for the bio-medical effects. These took two directions. One was a study of alteration in reaction time response in the primates after exposure to the micro-waves. The other was to implant a series of specially designed electrodes into specific areas of the brains of monkeys and to record the electro encephalographic changes before and after radiation.

(S) The studies on reaction times are inconclusive to-date. More data would be needed to express an opinion as to whether this approach should be pursued further or discarded.

(S) The E.E.G. approach has been carried out in association with The Brain Research Institute at the U.C.L.A. School of Medicine. The problem of artifacts and analysis of wave forms makes interpretation difficult. Further work in this area should be supported. To do this effectively, the analysis of the E.E.G. recordings should be on a "real time" or approximately "on line" analysis. This will require a computer availability and capability. The computer may be an in-house special purpose one, or a connection with a central computer programmed for this analysis. A cost effectiveness assessment of the alternatives should be helpful in the decision.

(S) The panel was of the opinion that the help of Dr. John Tukey of Princeton should be obtained. He is considered an outstanding expert in the field of wave form analysis.

(S) The WRAIR research workers presented two additional facets of the work. These were attempts to determine if there were any detectable morphological changes in the tissues. One effort was directed toward a study of the chromosomes of the circulating blood. The two animals studied to-date were reported as showing no changes.

This phase should be continued until a sufficient number of animals have been studied to give positive assurance that the non-ionizing radiation does not have any effect on chromosomes. The other was the histo pathological studies of the central nervous system tissues taken from animals that had been radiated. This study is being carried out at Tulane under contract. At the time of this briefing only one monkey brain had been studied. The contractor had reported that this brain was "different" from the controls. (The study is a blind one to avoid prejudice.) In view of the suggestive but inadequate evidence, additional effort must be made to further this aspect of the program.

(S) The panel recognizes that Col. Brady is a professional leader in the field of animal behavior studies and has added substantially to the credibility of the work.

(S) The response to Question #3 takes into consideration the total problem, including the animal findings as presented, and the time and cost element in extending animal studies to provide a more complete spectrum of response. In the absence of significant adverse findings in the chromosomal and histo pathological studies mentioned above, the future course of action must include a study of human response to non-ionizing radiation in low level fields and with the specific modulations employed in the primate exposure tests. Animal studies are only able to provide a limited spectrum of responses. The human with his ability to describe subjective changes can extend the response gradient through the levels: (*a*) Feelings, attitudes, fatigue, moods, etc., (*b*) Health, physical and mental, (*c*) Performance and stamina.

The animal studies are focused on (*c*) but may include (*b*); they cannot measure (*a*).

(S) Over a period of years humans have been exposed to micro-wave radiations at much higher field strengths than are proposed in this work. The U.S. personnel in the Moscow Embassy have been exposed to the micro-wave signal over a period of many years. The panel were not given any evidence of impaired health of these people.

(S) A protocol should be developed with the following objectives:

1. To determine the immediate or short time effects on humans of the synthetic Moscow signal in use at W.R.A.I.R. on the three aspects mentioned above. This should be given a high priority.
2. To provide for followup observations of the subjects.
3. The study should contribute to the understanding of the effects of micro-wave radiation on man in general as well as the specific Moscow signal.

(S) The protocol should be developed by the responsible group. This panel will stand ready to review the proposed protocol and offer such advice as they see indicated when asked to do so.

(S) It is suggested that the program provide for:

(*a*) Biochemical laboratory analysis of blood and urine for a variety of substances including steroids, enzymes, trace metals, etc.

(*b*) Cardiovascular evaluation such as E.C.G., blood pressure, etc.

(*c*) Chromosomal studies of lymphocytes cells.

(*d*) Appropriately sensitive and reliable studies on behavior.

(S) Subjects selected should be normal, healthy, young male adults. Exposure periods should be at least 90 days unless significant changes occur earlier. Subject should be divided into 3 groups:

1. Controls
2. Subjects with a history of exposure to micro-waves.
3. Subjects with no previous exposure to micro-waves.

(S) The panel at this time has no basis upon which to suggest the mechanism involved.

(S) It is recognized that the findings to-date were presented to the panel in an orientative way and the format of the presentation was qualitative. The panel suggests that the date be prepared in a statistical format for better scientific evaluation. The panel would like the opportunity to examine the data in depth.

LYSLE PETERSON.
JOSEPH KUBIS.
JOSEPH BARMACK.
FREDERIC HUGHES.
HERBERT POLLACK.

ADDENDUM

January 17, 1969.

The final results of the examination of the chromosomes obtained from the peripheral blood of one monkey, previously irradiated with the "Moscow signal" at a field strength of 4.6 mw/cm ^{2}, indicate marked aberations in 40 percent of the cells. The tests are being repeated.

MINUTES OF PANDORA MEETING OF JANUARY 17, 1969

Present a.m. and p.m.—Science Advisory Committee: General Frederic J. Hughes, Jr., Dr. Joseph F. Kubis, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack.

Walter Reed Army Institute of Research: Colonel Joseph V. Brady, Dr. Thomas W. Frazier, Major Joseph C. Sharp.

Dr. Joseph E. Barmack absent due to illness. Mr. H. Mark Grove, Wright-Patterson AFB. Commander Hugh S. Pratt, MC, USN (C.M.D. USS Saratoga). Rear Admiral Frank Voris, MC, USN.

Present p.m. only.—Dr. Joseph M. Aein, IDA, Mr. Richard S. Cesaro, OSD/ARPA/AS, Dr. James T. McIlwain, MC, USA, WRAIR, Mr. A. Rubenstein, OSD/ARPA/AS.

1. Dr. Pollack reviewed considerations relative to the USN–ARPA study to be carried out aboard the USS Saratoga currently in Philadelphia Naval Yard in preparation to join fleet operations.

2. Rear Admiral Voris and Commander Pratt commented on operational considerations of the study from money point of view.

3. Colonel Brady, Dr. Frazier, and Dr. Sharp commented regarding Walter Reed army considerations.

4. Mr. Grove commented regarding physical measurements and engineering considerations of shipboard radar measurements and monitoring.

Summary of Discussions.—Dr. Pollack reviewed need for definitive data on effects of radiation on physiological and psychological (particularly behavioral) functions in man. Primary areas to be looked at appeared to be (a) physiological, (i) formed blood elements, i.e., genetic alterations, (ii) cardiovascular and (iii) neurological and (b) psychological regarding task performance and group behavior. Regarding general plan involved selecting a population of ship's crew subjected to shipboard radiation (radar) and to compare them with a group below decks and not exposed to radiation. It appeared that plane handling crews on the hanger decks and flight decks involved similar enough tasks and living conditions that comparisons could be made so as to reveal any major or gross differences. Dr. Kubis and his team with the support of Commander Pratt and his staff aboard ship would review the personnel records of the two crew populations and select from them appropriate groups. They would receive physical and psychological tests during the approximately two weeks that the ship was scheduled to be docked in Philadelphia. Repeat tests would be made at intervals while the ship was underway and at certain scheduled ports-of-call during the following six weeks, a specific protocol was to be developed.

Discussion centered on selection criteria and upon what tests would be given to the selected groups.

Physical examination (including a general physical exam):

1. Blood specs for leucocyte genetic evolution
2. Blood pressure and pulse rate (on arising and after work cycle)
3. Discussion related to sending selected representation to the Philadelphia Naval Hospital for EEG evaluations. Also, a "microneurological exam" was described which might be included

Psychological examination was designed by Dr. Kubis and associates. Dr. Kubis indicated procedures would relate to cognitive, psychomotor, physical efficiency and sensory perception testing.

Three phases to protocol: I. Dockside—two weeks. II. Toward end of ten day shakedown. III. Three to six months later.

Meeting adjourned at 4:30 p.m. on January 17, 1969.

Minutes respectfully submitted by Lysle Peterson, Chairman.

SUMMARY OF PANDORA MEETING HELD: APRIL 21, 1969

I. Detailed minutes attached. Same classification and instructions.

II. Meeting organized in three parts:

1. Review of "Big Boy"

A. *Purpose.*—Elucidate effects on man of microwave radiation (radar) by comparing ship's crew groups apparently exposed to radiation to groups protected from radiation (below deck and remote stations). Studies on *USS Saratoga* in two stages (i) dock side in preparation for shakedown and (ii) shakedown, i.e., underway and operational.

B. *Findings.*—No significant differences in psychological tests performed on the apparently exposed and control groups. Also, no apparently significant differences on genetic (leucocyte) and physical findings. Thus, studies generally proved negative. Detailed report due from Dr. Kubis.

C. *Radiation Findings.*—Detailed survey of on-board radiation levels revealed that levels were considerably lower than anticipated, i.e., in most cases levels varied from 0.3 to 0.03 mw/cm^2 and in no case greater than 1 mw/cm^2. Radars were operating 80 to 90 percent capacity.

D. *Summary and Conclusions To Date.*—Saratoga study verified testing procedures and provided useful information for developing human radar-field testing. However, studies were negative since exposures were very low.

2. General discussion of ARPA contracts relative to biomedical effects of microwave

A. Dr. Brazie's studies of CNS tissue exposed to microwave radiation reviewed. *Recommendations:* to accelerate contractor's efforts as urgent and to extend samples. Attempt to get reports from contractor for inclusion in general report to panel as soon as possible.

B. Contract with Dr. Ross Adey reviewed. *Recommendations:* Although Dr. Adey's efforts bear on the general problem of the effects of radiation and fields on CNS functions, they are not directly contributory to priority ARPA questions. Since he is furnishing valuable EEG evaluation services as well as contributing to the general field, it was suggested that he be encouraged to deal more directly with priority questions and also to continue support for present. As Walter Reed capability develops, if contractors interests tend away from ARPA interests, support should be phased out.

C. New England Institute for Medical Research (Dr. Heller) program regarded as not contributing directly to ARPA high priority question although the contractor has capabilities in the area.

D. Work at Milton Zaret Foundation attempting to confirm or reproduce U.S.S.R. work. Review for information to panel.

E. The Lilienfeld studies conducted several years ago were reviewed, since a new proposal was being developed to extend the earlier studies. It was concluded that, due to the size of the Baltimore area mongoloid population and incidence, the scope of the study could probably not be increased by more than 50 percent. It was recommended that (i) scope not be extended beyond the Baltimore region, e.g., Washington area, (ii) that the program be regarded as a multiphase effort and that Phase 1 should be funded. If findings of Phase 1 indicated that further studies would be promising, then later phases could be considered for funding. Thus, proposal should include in-depth follow-up of original cases as well as new cases uncovered. See detailed minutes.

F. Studies of Dr. Dordano (Johns Hopkins), Dr. Sol Snyder, and Dr. Justison were reviewed for information.

3. General discussion

A. Priorities of ARPA interests in the microwave field were reviewed. High priority still assigned to evaluating the significance of Moscow Signal and also, in the general context, the biomedical effects of microwave radiation on humans such that meaningful safety standards can be set.

B. It was agreed that there is at present insufficient evidence to draw conclusions. In answer to questions about whether or not other studies (aside from those supported by ARPA) are likely to or have shed light on the problem, it was concluded that the only known study not included herein was that of Dr. Jacobson (George Washington School of Medicine) on young women exposed to Moscow Signal. Findings may indicate abnormal genetic activities in some of the women. Significance is not established. There was general discussion of chromosomal aberrations and its causes.

C. It was recommended that further studies be developed: (1) Walter Reed facility and program advancement be encouraged. Extend animal studies and initiate human studies. Suggestions for protocols were made, e.g., study include four men involved for six to eight months. Study to be in two groups and double-blind. (2) Programs to be developed to take advantage of land-based radar installations.

4. It was recommended that the Walter Reed group prepare and present a detailed review of the field, i.e., their activities with reports of their findings, protocols, etc., since projects were begun. Also, a review of relative contract work supported by ARPA and related to Walter Reed efforts as well as any related studies of others in field.

Respectfully submitted by Lysle Peterson, Chairman.

DETAILED MINUTES OF PANDORA MEETING OF APRIL 21, 1969

Present.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. H. Allen Ecker, General Frederic J. Hughes, Jr., Dr. Joseph F. Kubis, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack.

Walter Reed Army Institute of Research: Colonel Joseph V. Brady, Dr. Thomas W. Frazier, Mr. T. Daryl Hawkins,[1] Colonel Merrill C. Johnson, Major James T. McIlwain.

Mr. John F. Collins (CNO), USN.[1] Mr. H. Mark Grove, Wright-Patterson AFB. Mr. Albert Rubenstein, ARPA. Mr. Harris B. Stone (CNO), USN.

Dr. Pollack reviewed events since previous meeting. He noted the formation and meeting of a new committee (ERMAC**) from the Office of Emergency Planning and chaired by General James D. O'Connell to consider microwave radiation. This panel resulted from legislation setting HEW as the responsible agent for microwave radiation health considerations. He also noted that a document had appeared by Mr. Rexford Daniels under contract to the Office of Telecommunications Management. This document has been classified. He then noted that "Big Boy" shipboard exercise had been completed insofar as the dock-side and shakedown cruise activities aboard the *Saratoga*. Dr. Kubis would be submitting a report of activities and findings to date.

Dr. Kubis reviewed "Big Boy" objectives and events to date:

A. *Objective:* To study certain behavioral and physical functions of selected crew aboard the *Saratoga* in order to ascertain effects of microwave radiation on man regarding shedding light on effects of Moscow Signal, i.e., nonthermal effects (if any) of radiation of radar origin.

B. *Procedures:* 1. Three groups of ship's crew were selected:

(*a*) Flight deck crew (eight in number). Highest levels of exposure expected.

(*b*) Hangared deck crew (fiifteen in number). Low levels expected.

(*c*) Look-out crews (eight in number). No exposure expected.

2. Dock-side control tests conducted from Jan. 27 through Jan. 30, 1969. Five-man team under Kubis with excellent cooperation of naval medical personnel. (Details will be included in Dr. Kubis' report.) Batteries of tests included performance (e.g., aiming, depth perception, etc.) and written procedures. Also, base-line physical exams were given.

3. *Seagoing* tests were performed while ship was under way for shakedown cruise Jan. 30, 1969, through Feb. 10, 1969.

4. *Summary.*—Sixty-seven tests were performed in three days at dock-side, and ninety-two tests were performed at sea. Forty-seven tests represented retesting of control material. There were a number of disturbances regarding shipboard routine, etc., e.g., high noise levels, P-A system interrupted activities in "quiet room," general quarters intrusions into test areas due to routines variable

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[1] First attendance.

line voltage which affected equipment. Three dock-side test days conducted by five-man team; eight sea test days conducted by three-man team. It was regarded by Dr. Kubis that the testing was satisfactory and that the interruptions were not significant. Most test procedures were good (0.9); some were poor (greater than 0.1).

5. *Findings.*—There were no significant differences in the dock-side tests, i.e., among groups, and there were no significant differences among groups in the under-way tests, i.e., about 50 percent showed some increases in performance scores and about 50 percent showed some decreases. It was recommended that isolated power supply for instrumentation be developed if further work is to be done aboard ship.

Mr. Mark Grove reviewed the measurements and monitoring of shipboard radar levels. The ship was swept re two primary radiation sources, i.e., SPS–30 (S-band radar) and SPS–43 (UHF) search radar. It was expected from a naval electronics lab report that there might be greater than 10 mw/cm^2 on at least 80 percent of the surface of the deck (data from destroyers). Mr. Grove and Dr. Kubis were on ship at the same time but worked independently. Used RAMCORE dosimeter, HP power meter with thermoistor bridge (re S-band) from island to bow, 9 decks.

Findings.—In no case did measured levels exceed 1 mw/cm^2 with radar operations at 80 to 90 percent of utilization rate. Ranges of findings were in most cases less than 0.3 to 0.03 mw/cm^2. It was noted that verbal reports from shipboard engineers, i.e., engineering center and ship's hazards group, had indicated these findings. It was suggested that such reports had been made to the SEC.

C. *Discussion:*

1. Cover story considered appropriate and worked well (Robert Stone).

2. Aircraft radar and HERO effects were discussed. Effects and indications were insignificant.

3. Radiation from radar generators considered, i.e., 50 to 100 KV X-ray generation from tubes. Considered that lead shielding was adequate.

4. Mr. Rubenstein indicated that there were several excellent land-based radar sites which might be appropriate as study sites.

5. Blood studies from Saratoga crew were discussed. Colonel Johnson reported that twenty-one samples were recovered at San Juan. Seventeen successful cultures obtained with 288 spreads photographed. These were coded for double-blind studies. Code not yet revealed. Although two abnormalities were found, they were regarded as in normal range.

6. Several discussions of genetic aberrations of leucocyte nuclei covered several areas:

(*a*) Colonel Brady's three monkeys exposed to date at Walter Reed (thirty days) to special signals. One of these was the initial one showing abnormal chromosomal changes. Plan now is to get samples during exposure and with larger group of animals.

(b) Dr. Pollack reported the studies of Dr. Jacobson at George Washington University who has studied young women returning from embassy in Moscow (State Dept. contract). One hundred forty blood samples were examined over a four-year period of time. These specimens were identified only by code numbers. Four of these reportedly showed serious chromosomal abnormalities. Colonel Johnson reviewed these reported findings with Dr. Bender of Oakridge. The latter expressed the opinion that the evidence was based upon weighted data which may not be acceptable to all experts in the field.

(*c*) Dr. Johnson described the general character of chromosomal abnormalities re probabilities, stillborns, mongolism, chemicals, and drugs, etc. It was described that while bone marrow testicular tissue etc. might be better tissue to study (higher rates of replication), most knowledge is based upon leucocyte studies.

(*d*) The older Lilienfeld (John Hopkins) studies were of Korean and WW II veterans relative to the incidence of mongoloid children born to them. It was concluded that the earlier study was not well designed to reveal data regarding current interest. Study indicated that eighteen of twenty-five mongoloid children had fathers who had been exposed to radar. It is now proposed to expand the study in Baltimore and possibly in Washington. It is likely from the incidence and population of mongolism that the number cannot be increased beyond 50 percent, i.e., from twenty-five to about thirty-six. It was suggested that the original twenty-five and additional cases should be studied in detail, i.e., cytogenetic studies of testicles and lymphocytes. It is also concluded that the study may not answer the question. It was proposed that the study should cost $100,000; $50,000 from ARPA and $50,000 from NIH. The objective should be to validate the earlier study; i.e., cross-validation seems appropriate. The study may be regarded as in three phases. Phase 1 may be supported. Later phases should not be funded unless Phase 1 defines an appropriate study, i.e., a milestone decision should be made.

General discussion concluded that additional work is required to investigate whether or not appropriate radiation levels and type have genetic effects on man. Shipload versus land-based studies were discussed. It was concluded that land-based radar studies should be seriously considered and planned if appropriate. Details of George Washington University study were lacking to the group.

8. Dr. Brazies' (New Orleans) studies on material sent from Walter Reed are not completed as yet. Contractor does not know what the exposure is nor in which animals. (Does know that it is microwave.) He reported that one monkey (exposed to special signal) showed significant changes in the auditory and visual cortex but not in deeper structures. He is now studying two other monkeys and four dogs. These reports are due this year.

It was concluded that the contractor should be urged to proceed as rapidly as possible, i.e., with urgency.

9. It was concluded that more animals should be exposed and studied. There was discussion of the new facilities developing at Walter Reed. They are expected to be completed soon.

10. Contract with Dr. Ross Adey reviewed. Adey's studies have been concerned with modulated A.M. (3 to 10 cps) and C. W (4.6, 2 v/meter) and S–band radar modulated with EEG. He is continuing monkey studies regarding EEG and reaction-time. He has a contract with Northrup for the study of reaction times in electrostatic fields. It is felt that, although Dr. Adey's work is not directly concerned with the important questions of the effects of VHF on CNS function and that of excluding the electrical effects as artifacts, his work is related to the general field of the effects of radiation and CNS function. Also, he is assisting Walter Reed with EEG evaluation and data processing. Current level of support is about $135,000 annually. It was concluded that Dr. Adey should be informed that his own priorities and work trends are not entirely matched with those of ARPA. Although his work is related to the general field and is of considerable assistance to the Walter Reed effort, it is thought that his support might be phased out in a year or two after the Walter Reed facility is better developed.

11. A contract already funded by ONR with New England Institute for Medical Research (Dr. Heller) was reviewed. It was suggested that the content of this work is not directly appropriate to this subject although that institute has a microwave facility.

12. A contract with the Milton Zaret Foundation of Scarsdale, New York, was reviewed. Contractor also uses facilities of Brooklyn Polytechnical Institute. Work primarily in 700 p.p.s. (1–10 u. sec.) range. Is attempting to confirm or reproduce Myrra, Czechoslovakia, work, i.e., production of differences in heart rate at subthermal levels, This review was for information.

13. Other contracts were also reviewed: (*a*) Dr. Dordano of Johns Hopkins in A. M., F. M., C. W., S-band frequency work on monkeys. (*b*) Dr. Sol Snyder of Johns Hopkins is studying neuropharmacological effects, e.g., turn-over rates of norepinephrine and serotonin. (*c*) Dr. Justison (Kansas City, Missouri) using microwave Tappin oven is studying hypnotic and soporific effects of low power level microwaves. It is thought that the geometry of the oven may provide higher power levels than predicted.

14. It was estimated that current funding in the area is $500,000 outside and $200,000 in-house (does not include reconstruction and development costs at Walter Reed or computer facility).

15. It is regarded that the new facility providing three chambers and data processing including (Hewell Packard) general purpose computing, record and reproduce capability for time series, coherence, cross-and auto-correlations, etc., real time capability will be ready between mid-June and August.

16. The priority of questions of interest to ARPA was discussed. It was reiterated that the elucidation of the Moscow Signal remains as a high priority question with the general field of the effects of microwave radiation on man in order that safety standards may be rationally developed. It was also noted that, aside from the work of Dr. Jacobson, there was apparently no other relative work being conducted by Federal agencies.

17. The need for information on humans in addition to the accelerated animal studies at Walter Reed was emphasized. Therefore, it was urged that the Walter Reed facility develop a human program and start immediately to develop Phase 1, i.e., to develop a plan and protocols.

(*a*) Suggested putting the human aspect into the Pandora program rather than in the Walter Reed stress program.

(*b*) Estimated that human subjects would be required for six to eight months and that they could be obtained from Ft. Dietrich.

(*c*) Controls should also include as many variables as possible including IQ, memory and performance testing. Control period should be less than sixty days. One or more should go through the entire procedure without exposure, and one or more with alternating exposure plan. Study should be double-blind with protection of eyes and gonads. Shielding of testicles is recommended.

(*d*) Panel would like to review protocol before enactment.

18. Land-based radar station human study program should be developed to replace or supplement any onboard studies at sea.

Respectfully submitted by Lysle Peterson, Chairman.

MINUTES OF PANDORA MEETING OF MAY 12, 1969

Present.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. H. Allen Ecker, General Frederic J. Hughes, Jr., Dr. Joseph F. Kubis, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack.

Walter Reed Army Institute of Research: Colonel Joseph V. Brady, Dr. Thomas W. Frazier, Mr. T. Daryl Hawkins, Colonel Merrill C. Johnson, Major James T. McIlwain.

Dr. John F. Collins (CNO), USN. Mr. H. Mark Grove, Wright-Patterson AFB. Mr. Albert Rubenstein, ARPA.

(S) The primary order of business was the preliminary protocol proposal for human studies which was requested at the previous meeting on April 21, 1969. The protocol had been distributed toward the end of the previous week and, therefore, had not been received by many of the panel. Time to pursue the proposal was taken before discussion began.

(S) Dr. Brady noted that the proposal had been the combined effort of himself, Thomas Frazier, Merrill Johnson, and Daryl Hawkins and desired the advice of the committee on the ninety-day protocol. Dr. Brady noted that they had considered two basic strategies: (i) assumes that there is an effect of the signal (based upon previous experience) and the protocol is designed to maximize the yield and (ii) assumes that there may or may not be an effect (nue hypothesis) and the protocol would include "extreme" operations, i.e., high-forcing functions and large "n"s. If an effect is seen, then fine responses are defined.

(S) In view of previous experiences and evidence available, the first alternative was chosen, i.e., based upon the assumption that there is an effect. Therefore, protocol is an attempt to optimize economic considerations, use small "n"s and primarily to define the effects of the signal.

(S) The panel discussed the over-all strategy and alternatives and agreed with Dr. Brady. Also, re human experiments, this approach regarded most defensible as a prerequisite to more demanding studies, if needed.

(S) It was noted that a major question regarding any such study relates to the evaluation of behavioral effects since the spectrum of possibiilties is so broad compared to physical evaluation. Thus, the major part of the discussion related to behavioral aspects of the program. It was also noted that any energy form, if large enough, will produce biological effects. It was agreed that the signal used would be the special signal at the levels developed and used with the primates, i.e., between 4.5 and 5 mw/cm^2. Discussion revealed several distinct questions:

(i) Because the "n" is small (eight subjects) there, the question was raised as to whether the protocol will permit the characterization of the group, i.e., significance of the findings in individuals in a small "n" group.

(ii) To what extent is the instrumentation appropriate to carry out the objectives of the experiment, e.g., signal beam incidence, range of power levels, polarization, etc. The protocol had not detailed the electromagnetic aspects of the experimental design. Also, what are the effects, if any, of the signal on the instrumentation, e.g., EEG electrodes?

(iii) What are the dependent variables re behavior?

(iv) What are the considerations relative to monitoring the physical (biomedical) parameters re two purposes: as a monitor of the subject's general health and as scientific data re effects of signal?

(v) What are the classification considerations of the program re its management and scientific effectiveness?

(S)The discussion provided consensus regarding these points as follows:

DOD regards the general line of effort to aquire human-based data on effects of the signal, with appropriate safeguards, as a high priority. ARPA believes that the entire effort should be classified for several reasons. It was urged that DOD provide written security specifications and guide for the program.

(S) An appropriate cover relates to the purposes of the program to evaluate the validity of U.S.S.R. reports that nonthermal effects of nonionizing radiation are significant.

(S) It is urged that the special signal (or any improved signal, i.e., to better simulate the Moscow signal) be used. Currently, special signal-producing available equipment can develop less than 10 or 20 mw/cm^2. Monkey studies have been done at 4.6 mw/cm^2. Also recommendation to use same carrier frequency. While polarization can be varied, it was urged that the same polarization (radiation beam toward back of animal and vertical) be used in humans but that absorbent seat and gonadal protection be provided. While posterior presentation is utilized, protection of eyes should be considered.

(S) It was recommended that a medical examination function be established as a separate entity from the research function. Thus, the physical well-being of the subjects would be ascertained and reviewed periodically by medical expertise, which is not directly associated with the purpose of the effort. This medical examining function would not be privy to Pandora but would be given the cover story. It was noted that this separate examination procedure, if properly defined, could provide useful data as well as a safety check for the program. General Hughes thought that such a medical evaluation function could be arranged through the new commander of Walter Reed. In view of the fact that the morphological changes (cytological) which have been found in the CNS of animals exposed to the signal appeared in the visual cortex (as well as other areas), flicker fusion studies should be incorporated into the medical examination. Also, slit lamp and visual field checks should be made and audiograms done. It was also recommended that a separate psychiatric evaluation should be accomplished before and after the study. It was not resolved as to whether there should be separate psychiatric screening in addition to the research program screening procedures. This separate medical function or task force may be referred to as the "medical monitoring task force." It was recommended that a specific chain-of-command be established to be certain that in the changing personnel structure of Walter Reed. the appropriate responsibiilties are established, and thus, the research team will know whom to work through re the medical monitoring function. It was recommended that the medical monitoring procedure include:

Slit lamp examination: initially 90 days, 180 days.
Visual fields examination: initially 90 days, 180 days.
*Audiogram: initially 90 days, 180 days.
ECG: once per week.
**Physician perform general check-up once per week.
*At end of day.
**Have responsibility to be certain that all data are entered on record.

(S) Although the panel expressed some concern that the experiment, as defined by the protocol, might result in findings which would be difficult to characterize as definite indications of effects of the signal on man, i.e., the problems of characterizing changes in each individual and as his own control and of satisfying criteria of group statistics. It was recommended that at least one of the subjects and perhaps two go through the entire procedure except that they not be exposed to the signal. The fact that there are to be two rooms would facilities this approach.

(S) There was also continuing concern expressed regarding the effects of the signal on the measuring system itself, i.e., signal artifacts. The panel recommended continued scrutiny of this problem. The panel requested an up-to-date bibliography of the effects of microwaves on biological systems. It was noted that there is a recent article in the Canadian Journal of Microwaves.

Respectfully submitted by Lysle Peterson, Chairman.

MINUTES OF PANDORA MEETING OF JUNE 18, 1969

Present.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. James N. Brown[1], Dr. H. Allen Ecker, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack, Dr. Lawrence Sher.[1]

Walter Reed Army Institute of Research: Colonel Joseph V. Brady, Dr. Thomas W. Frazier, Mr. T. Daryl Hawkins, Colonel Merrill C. Johnson, Major James T. McIlwain.

Mr. Richard S. Cesaro, ARPA. Dr. John J. Collins, (CNO), USN. Mr. H. Mark Grove, Wright-Patterson AFB. Mr. Albert Rubenstein, ARPA.

Absent.—Dr. Joseph Kubis, Science Advisory Committee, Dr. Joseph C. Sharp, N.Y. State Dept. of Health, Mr. Harris B. Stone, (CNO), USN.

(S) The minutes of the previous meeting (May 12, 1969) were discussed. Dr. Peterson explained that the questions regarding the WRAIR protocol were stated as those which were raised for discussion at that meeting. The discussion associated with these questions resulted in a general agreement that the protocol in general provided an appropriate initial approach with human subjects. Furthermore, the nature of the problem together with constraints of available time, facilities, personnel and funds, and the scope of the approach result in statistical problems from the use of a small "n." A protocol using significantly more subjects would be more desirable but would delay the program considerably. It was agreed that for the first approach, the small "n" would be acceptable. The primary purpose of this meeting (June 18, 1969) was to consider the approach in more detail and to hear reports from ARPA and WRAIR regarding broad approaches to the solution of the Pandora and related problems:

(S) Mr. Cesaro reminded the Committee of the urgency and high priority which ARPA assigns to the Pandora program; it is important to make major advances in solving the problem in FY 70; the Advisory Committee was invited to give as much attention and creative thinking to the problem as it can. He defined the Advisory Committee's role and that its effectiveness would be enhanced by maintaining a close and continuing association with the Walter Reed group. His view of the overall problem was summarized:

1. Investigative programs should be designed to take major bites at the problem to achieve definite indications of whether or not there are effects on humans of microwaves under conditions simulating, as closely as appropriate, the Moscow signal. Furthermore, he urged that the experimental programs be relevant to the Pandora problem and provide significant results, negative or positive. He reminded the Committee that, conversely, it would be inappropriate to follow paths which while they might be interesting scientifically, would not be relevant to the problem.
2. While there is evidence that low energy (less than 10 mw/cm^2) R.F. radiation does penetrate to the CNS in primates, a significant and relevant question is how the penetration occurs, i.e., the mechanism re microwave characteristic and biomedical engineering principles. Such questions relate to whether or not the Moscow signal is unique and to whether the Soviets have special insight into the effects and use of athermal microwave radiation on man. The WRAIR experience indicates that C. W. has no effect, but modulation does.
3. There appears to be interrelationships of signal time and biological effects, which should be evaluated, i.e., biological on-off effects phased to the on-off character of the signal, i.e., short response times, intermediate and long time effects together with intermittent and long exposures, i.e., at least nine combinations possible.
4. The biomedical effects may include (i) physiological, (ii) behavioral, and (iii) genetic. Each general class re short and long time effects should be evaluated.
5. Man should be emphasized as the object in the investigations both because he is the obvious recipient and because he is in many ways a more effective reporter of effects.
6. Behavioral investigations should include attitudinal (subjective) considerations and measures.

(S) Discussion centered next on details of the WRAIR protocol. There was a consensus among the WRAIR and Committee members that the general approach of the protocol is appropriate and that in the initial stages of the effort, many "on-the-spot" decisions would have to be made because of the uncertainty of aspects of the program. As these uncertainties are clarified, the protocol would become better defined. The areas considered which require initial exploration to provide better definition are:

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[1] First attendance.

1. Exposure. It was the concensus that the aim should be to duplicate or simulate the Moscow environment as much as appropriate to solve the problem. Since exposure to the Moscow signal tended to be over an eight- to ten-hour period, it is thought that the exposure of subjects to he Special Signal should approximate that time frame. Furthermore, the primate findings were based on a seven-day, ten hours each day, exposure. It is suggested that the protocol indicate exposures up to eight to ten hours each day rather than the one-hour cycle providing four hours total per day.

2. The instrumentation artifact question re possible E. E. G. recordings be explored vigorously. The differences between primate and man with respect to head dimensions, effect of beam incidence, etc., must be reviewed and analyzed.

3. The physiological and medical monitoring include the array noted in the minutes of May 12, the matrix presented by Dr. McIlwain, portable ECG for continuous monitoring and the utilization of *lower-body, negative-pressure* plethysmography (LBNPP). It is recognized that the Soviet literature refers extensively to cardiovascular effects of microwave radiation. The nature of the reported behavior of the cardiovascular system requires relatively continuous monitoring to characterize significant effects from normal variations. Also, it is recognized that LBNPP is an accepted and relatively sensitive measure of cardiovascular "deconditioning" (in the physiological sense). In addition to the special tests, the medical monitor would be responsible for the routine physical examination, regular daily inspection of subjects and to adhere to the responsibilities associated with AR 70–25. These procedures would be worked out through the Office of the Surgeon General. Dept. of the Army, and jointly with WRAIR operational group and relative to security requirements defined by ARPA. ARPA agreed to present in writing, the security requirements for the program.

(S) The Committee recognizes that a period of uncertainty exists in the early phases of developing such a program and that the program director will require a degree of attitude in conducting pilot experiments before finalizing a detailed protocol. The Advisory Committee agreed to work closely with WRAIR in considerations of refinements of the protocol.

(S) The Committee agreed to conduct "brainstorming" sessions relative to the general Pandora problems in the context of ARPA's interests and responsibilities. The Committee expressed a need for more, yet manageable, literature review and information relative to the problem especially re the Soviet literature and from whatever sources useful information could be obtained. It was agreed that Dr. Pollack and Dr. McIlwain would assemble a "package" of useful documents to be distributed to the Committee. There are general discussion about various documents known to the attendees. It was agreed that several documents were relevant and appropriate, e.g., the IDA analysis due out soon, a document by Dr. Robert D. Turner, U.S.A Standards document, the ERMAC report, a report by Castlr and Dodge, one by Castle, one by Thompson, and the Presman summary. It was also agreed that ARPA would make available, to the Committee, any information that is relevant to the problem. It was also agreed that the agenda of the Advisory Committee would automatically include a call for a progress report and new, relevant information from Committee members, WRAIR, and ARPA.

(S) Dr. McIlwain and Data Corporation representatives presented a demonstration of the BEER project and application of a computer-based information storage and retrieval system to provide rapid access to files on microwave related information. It is expected that user needs and responses will soon be tested by ARPA and WRAIR.

(S) A correction of the minutes of May 12 is noted, i.e., that Dr. McIlwain participated as a principal in developing the WRAIR protocol.

(u) The next meeting is scheduled for July 16, 1969.

Respectfully submitted by Lysle Peterson, Chairman.

MINUTES OF PANDORA MEETING OF JULY 16, 1969

Present.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. James N. Brown, Dr. H. Allen Ecker, Dr. Joseph Kubis, Dr. Lysle H. Peterson, Chairman, Dr. Herbert Pollack, Dr. Lawrence Sher.

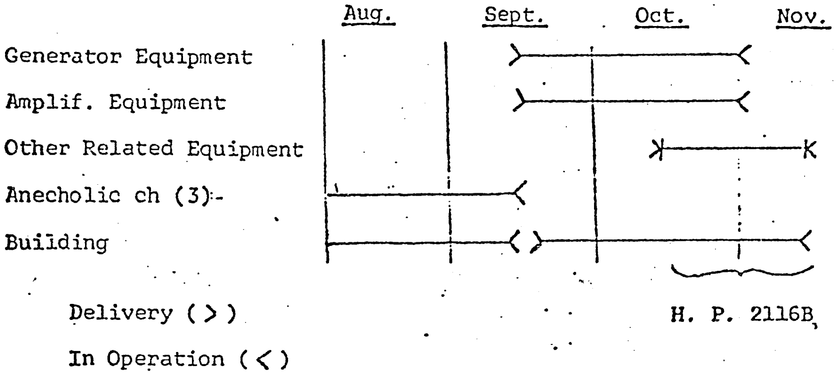
Walter Reed Army Institute of Research: Colonel Joseph V. Brady, Dr. Thomas W. Frazier, Mr. T. Daryl Hawkins, Colonel Merrill C. Johnson, Major James T. McIlwain.

Mr. Richrad S. Cesaro, ARPA; Dr. John J. Collins, (CNO), USN; Mr. H. Mark Grove, Wright-Patterson AFB; Mr. Albert Rubenstein, ARPA; Dr. Stanley Marder[1], IDA; Dr. Joseph C. Sharp, N.Y. State Department. of Health.

Absent: Mr. Harris B. Stone, (CNO), USN.

(S) The meeting was convened at 0930 at Building 503, Forrest Glen Annex, Walter Reed Hospital. The purpose of the meeting at Walter Reed was to review the developments of the facilities and programs re site, to review schedule for completion of the program and to give new Committee members the opportunity to see the laboratories.

(S) Major McIlwain and Mr. Grove led a presentation of schedules to complete the development of the facilities:



(S) Discussion included estimates of signal stability, flexibility, and obsolescence of system. Mr. Grove indicated that satisfactory stability could be expected re 15 ft. cube, that the system was modular and could be expanded, and that range extended from 250 megahertz to 10 gigahertz.

(S) Discussion then focused upon the relevance of the signals to the Moscow signal. It was stressed again that the signal used in the forthcoming experiments should (i) be comparable to previous experiments at the laboratory, (ii) be relevant to the Pandora problem, (iii) the signal characteristics be calibrated periodically as referenced to a standardization technique and (iv) possible signal artifacts (i.e., signals recorded from biomedical transducers due to direct effects of the microwave input in contrast to microwave input effects on the biomedical system) should be elucidated and evaluated.

(S) Discussion also focused upon the software program, i.e., the evaluation of data via computer system. Mr. Grove and Major McIlwain defined three software areas: (i) that developed by Ross Adey at U.C.L.A., (ii) that developed for the internal logic of the equipment to be delivered (H.P. 2116B and related system), and (iii) software needed to extend and interface with (i) and (ii). The U.C.L.A. program had been developed to test an array of statistical parameters re EEG signals on the equipment at U.C.L.A. WRAIR has selected from the total U.C.L.A. program certain aspects which were felt necessary for the WRAIR needs, e.g., auto- and cross-correlation, auto- and cross-power spectra, average transients and certain standard statistical processing. These were packaged into the logic of the equipment being delivered by Hewlett-Packard.

WRAIR felt that there were aspects of the U.C.L.A. programs (e.g., conference functions) that were not needed. To duplicate the U.C.L.A. software program would have been too costly and would require too extensive a hardware package. Thus, the special computer package approach was taken. It was not anticipated that extensive, additional software would be needed but that if so, contracting would be more appropriate than developing extensive in-house programming capability.

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[1] First attendance.

(S) In summary, the WRAIR presentation concluded that:

1. The facility (at least two chambers operational) would be ready for experimental work by mid-October unless unexpected delays occurred.

2. The signal characteristics would be comparable to previous work and that a calibration procedure would be adopted.

(Note: Discussion indicated that the calibration question related to defining the characteristics to be calibrated rather than to capability to calibrate, i.e., to define spectral and energy characteristics to be measured for calibration and standardization.)

3. With the planned program and facilities, the experimental artifact question could be approached within the inherent uncertainty levels. It is known that EEG experimental artifacts do occur and that the question remains as that in a given experiment how much of the recorded response is artifact, i.e., in levels at different EEG frequencies, to what extent is the living brain required. It is expected that the autospectral analogies will be helpful. A two- or three-month program using monkeys is planned.

(S) The Committee reconvened in executive session after lunch at Room 10K5 in IDA to review the present status of the program in the light of Mr. Cesaro's charge to the Commitee. It was agreed that the Committee would participate in certain working sessions devoted to specific problem areas and, whenever appropriate, do so in subgroups relative to the particular expertise involved, would conduct "brainstorming" sessions relative to the overall Pandora question and the various components of the program, and structure agenda for periodic, approximately monthly, meetings such that orderly progress should occur. Furthermore, contributors to the agenda would be invited as early as possible and notified of the material requested. A list of possible agenda items for the future was developed, and it was expected that this list would be considered appraised by Committee members and an agenda for the next meeting defined on or about August 1. It was agreed that the next meeting would be scheduled for August 12 and 13.

(U) The meeting was adjourned at 1700.

Respectfully submitted by Lysle H. Peterson, Chairman.

DRAFT

MINUTES OF PANDORA MEETINGS OF AUGUST 12 AND 13, 1969 (U)

Present.—Science Advisory Committee: Dr. Joseph E. Barmack, Dr. James N. Brown, Dr. H. Allen Ecker, Dr. Joseph Kubis, Dr. Lyle H. Peterson, Chairman, Dr. Herbert Pollack, Executive Secretary, Dr. Lawrence Sher.

The following attended Aug. 12 only: Mr. T. Daryl Hawkins, WRAIR; Major James T. McIlwain, WRAIR; Mr. Daniel Sullivan, ARPA.[1]

Absent.—Colonel Joseph V. Brady, WRAIR; Mr. Richard S. Cesaro, ARPA; Dr. John J. Collins, (CNO), USN; Dr. Thomas W. Frazier, WRAIR: Mr. H. Mark Grove, Wright-Patterson AFB; Colonel Merrill C. Johnson, WRAIR; Mr. Albert Rubenstein, ARPA; Dr. Joseph C. Sharp, N.Y. State Dept. of Health; Mr. Harris B. Stone, (CNO), USN.

(S) I. The minutes of the July 16 meeting were approved with minor modifications, such as the omission of the fact that the Committee had requested a written summary of the WRAIR program to date and an oral presentation of the basic data.

(S) II. Dr. Peterson reviewed the purpose of the meetings (August 12 and 13) as principally that defined at the previous meeting.

A. To have a detailed, full review presented by WRAIR of the background and findings of the Pandora/WRAIR primate studies from their inception to present. Specifically: (i) A review of the background for the development of the program. (ii) Considerations of the expected sensitivity and relevance of the tests used in the program. (iii) Review all findings from all experiments. (iv) Review current protocol for future program.

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[1] First attendance.

B. To hear Dr. Ecker's report on the work of his subcommittee, which was asked to look into the hardware systems being developed for future work in the program at WRAIR.

C. To discuss follow-up of Big Boy project. The Committee was then, in the remaining time, available to conduct "brain sessions," as requested by Mr. Cesaro.

(S) III. Major McIlwain presented his analysis and conclusions of the WRAIR/Pandora program. It is noted that although Colonel Joseph Brady, Dr. Joseph Sharp, and Mr. Mark Grove were invited, they were unable to attend this meeting. Also, Messrs. Cesaro and Rubenstein were unable to attend because of conflicting duties; however, they were represented by Mr. Dan Sullivan. The Committee's summary of Major McIlwain's review is as follows:

The experimental approach was defined early in 1966 mainly by Drs. Brady and Sharp with Dr. Sharp being assigned primary, direct responsibility for the operational conduct of the experimental program. The earliest studies were pilot studies. The same signal has been used throughout the study except for varied strength. This signal was selected from the "Moscow signal" tapes by a group representing various agencies. Mr. Mark Grove has had a major responsibility for providing the hardware to generate the selected "special" signal for WRAIR. Primate behavior measures were chosen by WRAIR as the primary indicators of an effect of the special signal. Studies comparing exposed and unexposed behavior were divided into three groups: 1. Reaction times, 2. Detection, and 3. Multiple schedule studies.

1. Reaction Time.—Two types of experiments were performed on two monkeys at 4.6 mw/cm^2: (i) *Shock avoidance* (No. 682) 250 trials/day in midday period and (Animal No. 683) 500 trials/day; both a.m. and p.m. periods.

Results: (a) No significant differences between experimental (exposed) and nonexposed periods, and no significant differences between a.m. and p.m. trials. was exposed to 4.6 mw/cm^2 at 11-second intervals. The second monkey was exposed to 20 mw/cm^2 at 60-second intervals.

Results: No significant detection elicited by either monkey.

Conclusion: The animals showed no response to the microwave signal at least in this regimen.

3. *Multiple Schedule.*—This was regarded as the most critical aspect of the experimental program and involved learning performances for nine sessions on four monkeys, using a progressive, fixed ratio reward (PRL) and alternating with a differential reinforcement of low rates (DRL). Six measures were examined using 4.6 mw/cm^2 as average field strength of the signal: (i) DRL distributions. (ii) Latency of the DRL. (iii) Average number of time-out responses. (iv) Average time per time-out. (v) Average pause time for each ratio step. (vi) Average running time within each ratio step. Of these, the only measure that showed any possible significant effect was the DRL distribution measure, but the data were internally contradictory. A further analysis was made of (i) the number of uninterpreted pauses exceding ten minutes, (ii) work stoppages for any reason, including equipment malfunction, and (iii) total number of pellets earned.

Results: In two of the nine sessions in which the full-power special signal was used, uninterpretable data were obtained either because of equipment malfunction or the use of reinforcement schedules (which reward certain types of stoppages) were recognized as contributing themselves to work stoppages. In two of the nine sessions, there was no effect of the signal; in three (or four) of the nine sessions, there were effects, but they were not cumulative; in one or possibly two sessions, there were unexplained work stoppages which, in the light of the total experience, appear to be random variations found as often in control as in exposed sessions.

Conclusions: There is no convincing evidence of an effect of the special signal on the performance of monkeys.

In addition, Dr. McIlwain acknowledged that the studies had primarily involved behavioral analysis with little effort made to analyze physiological functions, e.g., cardiovascular.

The Committee was told that Dr. McIlwain had not had the opportunity to present his analysis and conclusions to Drs. Sharp and Brady although he had briefly and informally conferred with Dr. Brady. Although the Commitee had not previously had any other detailed analysis of the WRAIR program findings, it was apparent that the conclusions presented earlier by Dr. Sharp were significantly different from those of Dr. McIlwain.

The Committee felt that because of the importance of these differences, the WRAIR program principals, Drs. Brady, Sharp, McIlwain, etc., should attempt to resolve the inconsistencies of their conclusions. The significant differences are, of course, whether or not there are established effects of the special signal on primate behavior as evidenced from the WRAIR program. It was also noted that no technical report had been written regarding the program to date. Dr. McIlwain agreed to furnish the Committee with a written summary of his presentation. The Committee expressed the desire to analyze the raw data themselves.

(S) IV. Dr. H. Allen Ecker presented the findings of his subcommittee on the functions and characteristics of the instrumentation being developed for the expanded WRAIR program. (See minutes of July 16.) A written summary of Dr. Ecker's report is appended (Exhibit A). In discussion, it was concluded that the capacity of the instrumentation exceeds present requirements, but the rational that if the program is expanded and extended, that added requirements will develop, is probably sound.

Discussion regarding the special signal was withheld until after Dr. Ecker's presentation although this major attempt to duplicate it must start from a thorough analysis. To date, the analysis has not, apparently, been thorough; a deficiency in the Pandora effort.

Mr. Daniel Sullivan of ARPA was requested to see whether the signal analysis could be made available to the Committee.

(S) V. A brief review of Big Boy reminded the Committee that the results of the Saratoga study were essentially inconclusive although the testing technology and programs were worked out and proved feasible and reliable with certain suggested improvements. (A report has been written of the Saratoga effort.) A possible reason for the inconclusiveness of the Saratoga study was that the levels of microwave radiation measured at sites where tested personnel were located were found to be extremely low and the exposure time very slight. The Committee recommends that the approach of using established, operational radar stations to test the effects of microwaves on humans be followed-up. Dr. McIlwain indicated that he and Mark Grove had looked at the possibilities of several ground-based establishments, such as those at Monmouth, White Sands, Fort Sill, Hawk missile systems (e.g., El Paso), etc. Their conclusions are that populations of men exposed to radiation are too unstable to be effective for tests. It was also noted that the Navy has at least seven communications * * *

INSTRUMENTATION REVIEW

On 31 July 1969 Dr. James N. Brown, Mr. Mark Grove and Dr. H. Allen Ecker met at Georgia Tech to review the planned instrumentation for the new facility at WRAIR. Since the schedule for completion of equipment was discussed at some length at the last Pandora Panel Meeting and is recorded in the minutes of that meeting, further discussion of the schedule did not appear necessary. The two major items that were reviewed are (1) the Signal Generation Equipment and (2) the Data Recording and Processing Equipment. Neither the variables to be measured, the method of their measurement nor software requirements was discussed.

Data recording and processing equipment

A simplified block diagram of the Data Recording and Processing Equipment for the new facility is shown in Figure 1. Hewlett-Packard is the prime contractor for design and installation of this system and a very flexible and well-coordinated system which offers excellent data analysis capability has been designed. The use of pre-programmed analyzers such as the new Hewlett-Packard 5450 Fourier Analyzer provides pre-programmed analysis techniques and therefore, reduces the initial software requirements. Both analog and digital data storage equipment is included. Care has been taken to provide calibration and monitoring capability throughout the system. Since the variables to be measured and analyzed were not defined at the time of equipment design, it appears that the money available for this instrumentation was used wisely to provide a very flexible data recording and processing system.

A suggestion for increased capability is the use of a Honeywell Visicorder in place of the currently planned HP 7878 Ink Oscillograph. The visicorder offers a bandwidth of 5 KHz with an extension to 10 KHz with reduced amplitude; whereas the HP Ink Recorder has a maximum bandwidth of 150 Hz. In any system in which input variables are unknown, bandwidth can be a limiting factor on flexibility of the processing system.

Signal generation equipment

The task of designating the system to generate the desired RF signal was accomplished in house with Litton Industries providing the special high voltage power supply. A preliminary block diagram of the basic components of the system is shown in Figure 2. The basic RF oscillator is an HP 8690 Sweep Oscillator. The frequency modulation signal is generated by summing the output from two Hewlett-Packard 3300 Function Generators and a General Radio 1390 Noise Generator; current plans do not call for amplitude modulation. However, a PIN modulator could be inserted between the basic oscillator and the first amplifier as indicated by X on the block diagram. A PIN modulator is an easy and flexible way to provide amplitude modulation with minimum interaction with the desired frequency modulation.

A two stage drive section in the form of sequential 1 watt and 10 watt TWT amplifiers is part of the present design. TWT's with 30 dB gain are common; therefore, in a conventional system, drivers separated by only 10 dB in output would not be an efficient system; the desire for extreme linearity prompted the choice of this configuration.

Provisions are made to monitor the power level and the frequency spectrum after the 10 watt TWT. The results of this monitoring will be available to the Data Processing System.

The present plans call for Klystrons to amplify the signal to a 1-to-12 kilowatt level. An amplifier of this type in the frequency range of interest would have only approximately 5 MHz bandwidth with 40 dB of gain. Since only about 23 dB of gain would be required to produce 2 kilowatts from a 10 watt drive, it would be possible to stagger tune the Klystron amplifier sections and increase the bandwidth at the expense of gain; perhaps as much as 15 or 20 MHz bandwidths could be achieved. A major design item in the Signal Generation System is the high voltage power supply and associated protective circuitry for the Klystron amplifier. At present, a 10 kilowatt-1 amp power supply is being designed.

After the Klystron amplifier, monitoring of the output power will be provided as well as isolation from undesired or reflected signals. The transmitting antenna will be a Scientific Atlanta Standard Gain Horn with approximately 18 dB gain. The three dB beamwidths in the E and H planes are 23° and 22° respectively. A probe antenna and associated thermistor mount and power meter are provided down range for monitoring power levels at that point.

The signal generation system as proposed provides a flexible source for a frequency and amplitude modulated RF signal with the exception of the final Klystron amplifier. Octave bandwidths are common practice in TWT amplifiers whereas Klystrons usually exhibit less than a one percent bandwidth. If one is assured that the signal to be simulated will never exceed the bandwidth limitation of the Klystron amplifier, then the proposed system will be adequate. However, if the possibility of a larger bandwidth requirement exists, the search for broader bandwidth and perhaps higher powered output tubes should be made. Both Hughes and Varian advertise 1 KW CW TWT amplifiers in the frequency range of interest. A recent advertisement by Varian in the March 1969 Microwave Journal indicates that 10 KW CW TWT's have been built and delivered. Also, recent developments in CW cross field amplifiers could provide a very efficient and reasonably broadband final transmitter stage. Both Ratheon and SFD have made significant advances in the development of cross field amplifiers. It should be emphasized that the system was originally conceived before the above tubes were catalog items. Also, cost and scheduling can be limiting factors.

The choice of a standard gain horn for the transmitting antenna provides a simple method of coupling to free space. However, the far-field criterion must be satisfied to establish a uniform plane wave over a region in space. If a larger area and a more uniform wave is desired, a large collimating reflector type antenna could be substituted for the standard gain horn. Of course, a large reflector antenna would be much more expensive.

Concluding remarks

The results of the review of instrumentation indicate that at this point both the Data Recording and Processing System and the Signal Generation System have been well planned. However, two pressing issues must be resolved. (1) It is imperative that rapid decisions be made on the variables to be measured and on the desired methods of analyses to permit determination of required software. (2) A more thorough analysis of the RF signal to be simulated is necessary. The bandwidth requirements of the output amplifier hinge on the results of that analysis.

Respectfully submitted,

H. ALLEN ECKER.

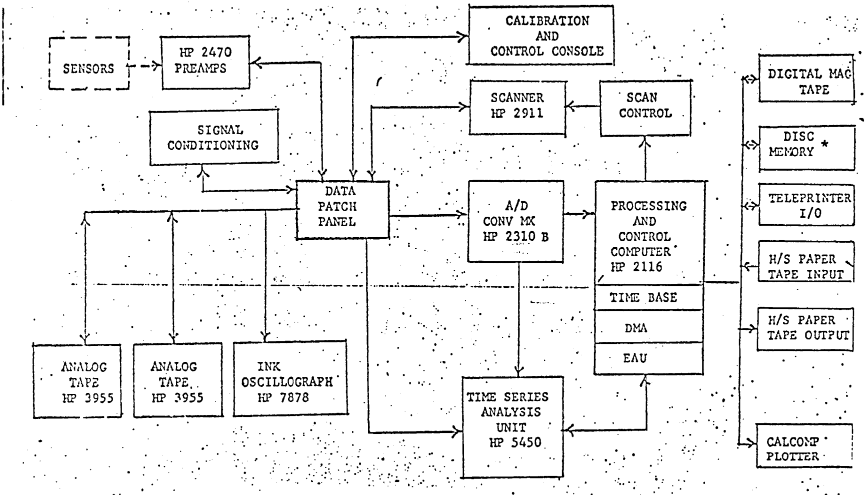
SENSORS
HP 2470 PREAMPS
SIGNAL CONDITIONING
CALIBRATION AND CONTROL CONSOLE
SCANNER HP 2911
SCAN CONTROL
DATA PATCH PANEL
A/D CONV MX HP 2310 B
PROCESSING AND CONTROL COMPUTER HP 2116
TIME BASE
DMA
EAU
DIGITAL MAG TAPE
DISC MEMORY *
TELEPRINTER I/O
H/S PAPER TAPE INPUT
H/S PAPER TAPE OUTPUT
CALCOMP PLOTTER
ANALOG TAPE HP 3955
ANALOG TAPE HP 3955
INK OSCILLOGRAPH HP 7878
TIME SERIES ANALYSIS UNIT HP 5450

FIGURE 1

9 August 1969

* Not part of original purchase

ON THE EVALUATION OF DATA ASSOCIATED WITH PANDORA

Preliminary Report by Joseph A. Kubis 12/4/69

SECTION 1: INTRODUCTION

Found

In a letter dated October 29, 1969, Dr. Lysle H. Peterson invited me to help in "developing criteria for the evaluation of data associated with Pandora." I agreed to talk with the project investigators, examine whatever records were available, and prepare a report of my findings and recommendations.

My purpose in meeting with those intimately connected with the project was to solicit ideas on how they felt the data should be evaluated. The examination of basic and derived data was not only to gain an understanding of the analyses already made but also to recommend additional procedures the structure of the data might suggest.

Finally, I suggested that whatever findings and recommendations I would make be reviewed by Dr. Peterson, who with the assistance of Dr. Pollack, would decide whether further effort on my part would be desirable.

Problem

The underlying problem which led to this report was the existence of two different approaches to the analysis of Pandora data—one by Dr. J. Sharp, the other by Maj. J. McIlwain. In Dr. Sharp's view, although most of the experiments produced negative results, certain aspects of the data (IRT changes and work stoppages) are suggestive of an exposure effect due to the WRAIR signal. Admitting that some changes in the animal's behavior could not be explained by artifacts, Maj. McIlwain believes that there is insufficient consistency in the data to seriously entertain the notion of an exposure effect due to the special WRAIR signal.

The evidence adduced by Dr. Sharp was a series of graphs and a cataloguing of the instances of work stoppages attributed to the special signal. Maj. McIlwain's position is that there are clerical errors in one of the graphs and that the sequence showing a shift in the IRT distribution is a function of the days selected for graphing. He has presented graphs from baseline periods that are similar to the graphs in the IRT sequence. As for work stoppages, Maj. McIlwain noted that a number of them could be associated with mechanical and other failures. Acknowledging that such difficulties limit interpretations, Dr. Sharp believes that there are some runs that are artifact-free and that these should undergo intensive analysis.

Appointments were made with the following individuals associated with Pandora: Col. J. Brady, Col. E. Buescher, Mr. R. Cesaro, Maj. J. McIwain, Col. W. Meroncy, Mr. A. Rubenstein, Dr. J. Sharp.

During these visits a number of reports were examined as well as the basic and derived data from the experiments. A description of the visits made and the materials examined may be found in Appendixes A and D.

SECTION 2: COMPONENTS OF THE PROBLEM

As stated in Section 1, the problem seems simple enough. However, it is embedded in a mosaic of components, which, if clearly understood, will place the problem in proper perspective.

Project as a whole

Essential to a proper evaluation of the problem is the consideration of how the project as a whole was viewed. Dr. Sharp interpreted his task as exploratory in nature—a series of pilot experiments to search for leads that might prove fruitful in a more extended research effort. An examination of the experiment protocols does support this interpretation: many experiments were tried, many conditions were tested, and many changes in procedure were introduced during the experimental program.

The inevitable outcome of a pilot program is an accumulation of a wide diversity of data, fractionated into blocks obtained under various combinations of conditions. Experimental outcomes, uncontaminated by changes in condition or possible influence of several factors, are hard to come by. A particularly pertinent example from the Pandora experiments may be found in Appendix C.

A second consequence of a pilot program is that conclusions cannot be asserted with great confidence because of the limited number of observations that are available. Statistical tests performed on even promising segments of data might very well lead to insignificant results because the sample size is small.

From the nature of the case, then, the conclusions generated from the Pandora experiments at WRAIR must be considered as tentative and suggestive except for segments of data sufficiently numerous and free from the contaminating effects of changes in condition or intrusion of uncontrolled factors.

The WRAIR experimental program contains an imaginative complex of procedures which tap various behavioral functions that are uniquely packaged into a well-motivated work day for the monkey. A description of the various "jobs" comprising the monkey's work day may be found in Appendix B.

As structured at present, the experimental program generates data from the same monkey exposed to a variety of conditions. At times he is exposed to a variety of conditions. At times he is exposed to a signal, at times not. Each monkey is his own control. This is an efficient design provided that a minimally varying baseline can be achieved, that the baseline is stable over relatively long periods of time, that the behavior observed is sensitive to the experimental "intrusion," and that strict control over most of the confounding conditions can be maintained throughout the experiment. When these conditions cannot be easily met, the design can benefit appreciably from the inclusion of control subjects.

From an interpretative point of view, it is felt that the results of the Pandora experiments would have been more discriminative with the addition of control animals. In particular, it would have been desirable to control for the effects of "isolation" and "confinement." Over a long period of time, say several months, it is possible that continued isolation and confinement could bring about an erratic temporal pattern in the monkey's performance.

One further point about procedure. The complexity of the present task routine makes inevitable a long turn-around-time for a single animal. He requires a long training period and is subjected for a long time to a stimulus whose measurable effect may be long delayed. Inevitably this means that the experiment is based on a small sample with an effect that may be weak or ephemeral. In turn, this leads either to very limited generalizeability or to inconclusive statistical results. At worst, it could lead to accepting as significant results that reflect long-range and unknown fluctuations in the animal's condition in no way related to the experimental signal. Expanded facilities, of course, would help since more experimental and more control animals could be used. In addition, the use of tasks or animals with a shorter turn-around-time should also be considered.

Flaws in test conditions and baseline

As mentioned earlier, test conditions were changed relatively frequently. Some changes were due to limitations of test facilities, for example, having the animal tested or trained in the "ice box" and then tested in the anechoic chamber. In other cases, changes were introduced to determine if a facilitating or debilitating effect would ensue, as, for example, changing the character or strength of signal exposure. In any event, the greater the number of changes in conditions (especially if used in combination), the smaller the chances that an adequate baseline would be obtained to test for the specific effect under consideration.

As illustrated in Appendix C, the animal was exposed to a number of differing conditions in various combinations within a relatively short period of time. These were: night vs. day work, alone vs. with another animal, "ice box" vs. anechoic chamber. WRAIR signal on vs. WRAIR signal off, new chair, new lever, new speaker vs. old chair, old lever, old speaker. Good baselines for testing the effects of all these changes might prove impossible of attainment.

Adequacy of baseline is a serious but not hopeless problem in the WRAIR experiments. The basic shortcoming is that the number of observations for the appropriate baseline may be small.

Functioning system

The usual mechanical difficulties were experienced during the course of the Pandora experiments: feeder jam, empty feeder, ink failure, etc. Power fluctuations and circuit malfunction also occurred.

One of the obvious results of such malfunction is loss of data. The problem, however, is more complicated. It is very likely that the finely trained animal may have had his habit patterns disturbed because of the inappropriate cues or inadequate food rewards. His "confusion" and altered motivation may have affected his behavior for the remainder of the day and possibly for a day or more after the malfunction. The fundamental questions are: Subsequent to the identified malfunction, how much data should be discarded as unreliable? How reliable is the data immediately before the difficulty was identified?

Relevant criteria for these situations may have been developed by the laboratory in the course of its experience. In any event, an informed opinion to corroborate the adequacy of such criteria should be obtained from an outstanding expert in the field of animal experimentation. It is suggested that such information be obtained from Col. J. Brady.

Analytic procedures, etc.

Interpretation of data is strongly connected to the model assumed to underly the data. Similarly, the model will tend to determine the character and direction of the statistical procedures one would employ to analyze the data. As a simple example, the model may specify that the exposure signal enhances the functioning of the organism, or that it causes a deterioration in its functioning, or that it enhances some functions and brings about a deterioration in others, or that it has no observable effect at all.

The analysis and interpretation of the Pandora experiments will depend, then, on the characteristics of the model one considers appropriate for the data. For example: Is the effect cumulative (or non-cumulative)? Is the effect reversible (or irreversible)? Is the effect ephemeral, so that it is generally observable only under direct exposure?

One must take into account that the level of significance for the statistical tests is no longer the conventional one agreed upon. In a similar vein, as one tests more and more relatively independent variables within the same experiment, one is likely to obtain some results that seem to point to a statistically significant effect when, in reality, there is none. This is analogous to the traditional urn problem (containing, for example, 95 white and 5 red balls) in which the probability of picking a red ball in one draw is .05. Yet the probability of obtaining a red ball increases rapidly as I make many successive draws from the urn (replacement model).

The Pandora experiments reflect a multivariate model embedded in a time series. Although the multivariate time series model is not recommended for the present set of Pandora experiments, some thought might be given to its use when a critical and definitive set of experiments is decided upon.

SECTION 3: RECOMMENDATIONS

Basic issues

Work stoppage.—A relevant scale needs to be developed for the application of this concept. In Maj. McIlwain's analyses an animal who "stopped work and did not recommence within ten minutes of the end of the day" is said to have engaged in a work stoppage. As used in a nominal-scale situation, a work stoppage of 11 minutes is equivalent to one of several hours.

It is recommended that the distribution of the lengths of work stoppages be compiled so that the parameters of the distribution can be estimated. This should help in establishing a weighting procedure which would give more weight to longer than to shorter work stoppages. (Often in the case of time variables, a logarithmic transformation provides an adequate solution.)

Distribution shift.—In his presentation of a series of overlays (exposure data) compared to a distribution of baseline data, Dr. Sharp can be challenged concerning the criterion he used to select his time points. If this criterion had no theoretical jurisdiction, then distributions at other time points could have been taken just as well. What Dr. Sharp wanted to show is a global trend of the distributions without the necessity of processing all the data. Maj. McIlwain's "counter examples" taken from baseline data, though pictorially effective, may suffer from a similar selection bias.

Two analytic approaches seem to be feasible: (1) studying the change in the distribution as a whole over time; (2) utilizing several appropriate parameters of the distributions and studying their trend over time.

A first approach towards evaluating the change in the distribution as a whole over time might consider fractionating a time period into successive segments and then constructing an "average" distribution for each segment. The differences between distributions could be tested by a Kolmogorov-Smirnov type of statistic. This test procedure could be improved by the development of a Studentized range type of statistic for total distributions analogous * * *

In the second approach mentioned above, several basic parameters would be estimated for each distribution at each time point. The median and interquartile range would be appropriate. The distribution of these statistics over time would be available for analysis. Often enough, the hypothesis under test is relatively simple, as, for example, that the median (or interquartile range) increases over time. Curve fitting procedures could be used to test this or more complex functions. Orthogonal polynomials also could be utilized in testing for trend.

Either of the two approaches should be used. Of these, the trend analysis would seem more feasible, at least initially. The statistics (median and interquartile range) are available and the test procedure is characterized by ease of computation and interpretation.

Baseline problems

From an examination of the data and the graphs based on the data, it would be a questionable procedure to use many of the original baselines to evaluate the effects of the WRAIR signal. For example, the baseline developed in the "icebox" is not relevant to test for the effect of the signal in the anechoic chamber. Similarly, a baseline developed on a night "shift" cannot be used to test the effects of the WRAIR signal given during the day. Discouraged by the problem of an adequate baseline, Maj McIlwain has refrained from using baselines in his analyses of the exposure periods.

It is recommended that the initial period of orientation to any change in condition be considered as a source for baseline data. For example, after transfer from the "icebox" to the anechoic chamber, the animal is usually tested for a number of days without exposure to the WRAIR signal. A portion of this adaptation period, once the perturbations settle down, could be used as the base against which the effects of the signal should be evaluated. Despite the fewer number of points available, they should be used as baseline data for the particular comparison under consideration.

The issue pointed up in this discussion is that there is no general baseline for all combinations of test situations. Changes in test situations seem to produce more pronounced effects than exposure stimuli.

Division of exposure period

In the extant analyses, Maj. McIlwain has divided the exposure period into two equal segments. He has reasoned that if the effect is cumulative, the average value of the two segments should differ—the greater effect being observed in the second half of the exposure period. This analysis loses some valuable information. In the first place it gives no information about the comparison of the exposure period with the * * *

It is recommended that the exposure period be divided into more than two segments. In particular, since it is anticipated that the new baseline periods will not contain many points (confer discussion in the previous section), it would be advantageous to divide the exposure period into segments equal in size to the baseline period. The analyses, nonparametric analogues of analysis of variance, will have the following advantages: (1) a comparison with baseline data will be available, and (2) a trend would be more discernible and easily tested.

Typical considerations

Where hypothesis are specific and directional, one-tailed tests should be used. The possibility of an enhancement effect on some functions under exposure should not be discounted. Two-tailed tests in these situations would leave the issue open ended.

It is recommended that the personnel at WRAIR continue using nonparametric statistics wherever feasible. These are the statistics of choice since the distributions of many of the statistics used in behavioral measurements have no known parametric representation. Further, they have good efficiency and they are simply and easily calculated.

It is also recommended that these calculations be done by clerical personnel trained and supervised by Maj. McIlwain.

It is urged that the operational definitions of relevant concepts (ex. pause), the specification of models, evaluation of effects of malfunction, rejection of inadequate data, and other such problems be discussed with the expertise available in-house at WRAIR. In particular, the services of Col. J. Brady should be secured, since he is an outstanding authority in behavioral matters, especially those pertaining to animal behavior.

STATE OF ALABAMA,
DEPARTMENT OF PUBLIC HEALTH,
Montgomery, Ala., June 15, 1977.

U.S. SENATE,
Committee on Commerce, Science, and Transportation,
U.S. Capitol, Washington, D.C.

GENTLEMEN: This letter is in response to your questions at the Conference of Radiation Control Program Directors as part of their testimony to be given on June 29, 1977.

(I) We have reviewed the program and conclude that there are several areas which need resolutions or are of concern to the consuming public. Some of these issues may not require legislation but either changes in regulations or an approporiate policy decision. These areas are as follows:

(*a*) *Radium and Other Non-Agreement Radioactive Materials.*—As the Committee is aware, all source material, special nuclear material, and byproduct materials are covered by the Atomic Energy Act of 1954, as amended. Regulatory control of these materials is currently vested in the U.S. Nuclear Regulatory Commission or by special agreement in Agreement States. There are other radioactive materials such as radium which are not presently regulated by any federal agency; however, most, if not all, of the Agreement States regulate these materials similarly to source, special nuclear, and byproduct materials. The fact that some twenty (20) states do not license the users of these non-agreement radioactive materials is a gap in their control. Each Agreement State can cite several instances where these non-agreement materials have been transferred to unlicensed users from Non-Agreement States. In some cases the equipment being transferred did not meet minimal standards or give any indication that it contained radioactive material. Currently the Bureau of Radiological Health of the BDA has a voluntary program to identify equipment containing these materials. While this is an improvement over the situation that existed several years ago, we still are having materials distributed to non-licensees, improperly labeled, or with other questionable manufacturing practices.

We suggest that the Atomic Energy Act be amended to include these products so that they are regulated like byproduct, source, and special nuclear material. As an alternative, you may wish to amend the Radiation Safety Act of 1968.

(b) *OSHA.*—The Occupational Safety and Health Administration has comprehensive regulations for all health results in the work environment. It has been our experience with OSHA that, in general, they do not have sufficient trained personnel to adequately protect the worker from ionizing radiation. Indeed, virtually every state is doing as many inspections for ionizing radiation alone as OSHA is doing for all other safety and health matters. In addition, most states have specifically trained personnel to do their ionizing radiation inspections. For example, in Alabama everyone inspecting radioactive materials has a Masters Degree. Those inspecting x-ray equipment are registered x-ray technologists and have an additional month and a half specialized radiation training plus three (3) months on the job training.

Presently OSHA's regulations do not totally recognize good health physics practices. Further, in attempting to work with OSHA, they are totally against any state applying to control a single standard such as ionizing radiation. They would accept an application to control a group of standards but not a single standard. In view of the limited resources of individuals trained in the regulation of ionizing radiation as well as the recognition that most states have an ongoing program in ionizing radiation, it would be well for the Committee to consider designating one agency for all regulatory items involving ionizing radiation: and such an agency should utilize to the greatest possible state capabilities similarly to the NRC Agreement State program. As a philosophical point, it would probably be wise to have a different Agency establishing radiation exposure standards.

(c) *Disaster Planning.*—This area of radiation operation has been subject to much public comment, most of which does not leave a true impression of the state of emergency planning. In general most communities can take the necessary protective actions on a timely basis from any hazardous threat normally encountered at peace time; however, that is not to say that improvements should not be made. It has been our experience that the local and state governments are prepared and will take the necessary actions of clear lines of communications and authority are established between the various concerned agencies.

Current federal efforts leave us with several basic impressions:

(1) All emergency planning must take the form of a quasi-military operation or is merely a modification of the nuclear warfare concept. We do not agree that a community will be totally unable to get advice and technical support during a radiation emergency as would occur during a nuclear war. This subtle but significant difference does not appear to be recognized by all federal agencies.

(2) There is a lack of definition of what accident criteria state and local plans should be capable of coping with. Expressed another way no one has told the state and local agencies what accidents have sufficient probability to the expenditure of public mones to design a radiation emergency plan. As an example, everyone knows that it is possible for a 747 to crash into a Super Bowl game with resulting large numbers of fatalities and injuries. We are unaware of anyone who thinks this probability is sufficient to develop a detailed disaster plan for this occurrence. The State of Alabama has since 1971 endeavored to obtain a statement from the federal agencies as to what accident conditions for which we should write a detailed radiation emergency plan. As of this date, such information has not been provided. We understand that it will be provided in the near future.

Because of this lack of accident definition, the State of Alabama and other states have recommended against participating in the NRC's concurrence program for radiation emergency plans for fixed facilities. It does not seem logical or even possible for one to write an emergency plan when the scope of the accident is different for each agency who reviews the plan; however, once there is a general agreement on the accident or accidents for which radiation emergency plans should be prepared, then we believe we can support the NRC's Concurrence Program.

Current guides prepared by the federal agencies are open to interpretation and indeed is contradictory. For example, current NRC regulations define an accident which is used to evaluate the suitability of a specific site; yet, when one takes their emergency planning document, "Guide and Checklist for Development and Evaluation of State and Local Government Radiological Emergency Response Plans in Support of Fixed Nuclear Facilities", NUREG 75/111, one finds under L3 that one is required to have maps showing the physical location of all public, private, and military hospitals or other emergency medical service facilities within the state considered capable of providing medical support for any off-site victims of a radiological incident. Further, these facilities are expected to have trained personnel to care for victims of radiological accidents. At first glance there seems to be no problem until you try to get a decision about the injuries these medical facilities will be treating. Are we to expect several hundred individuals suffering from the radiation syndrome, or are we talking about those people who may be involved in car accidents, etc., during an evacuation? If it is the former, then it is inconsistent with the NRC regulations for design based accidents (DBA), which would not require medical attention. If it is the latter, experience with evacuations shows that you will not need a map of all the medical facilities in the state, nor will you have seen unusual medical problems to require experts to be imported from all over the state. This is just one example of many in which federal agency guidance is inconsistent and confusing.

Regretfully, many federal people envision a situation in which the local community will be unable to get timely technical advice during a radiological emergency. Using this concept, many have proposed using nuclear warfare instrumentation to attempt to evaluate the radiological situation. Indeed they point with pride at how many millions of instruments have been distributed and how many have been trained in their use. Unfortunately they forget that much of the training occurred over ten (10) years ago and that it was oriented to strictly wartime conditions. Further, they conveniently forget that the instruments were designed for particulate fallout and not for gaseous releases which are the most likely releases from nuclear powerplants. One should be aware that many police and fire departments have been given updated training with these instruments, and indeed our own Division has supplemented the training in some cases. I would not suggest that anyone should ignore the availablity of instrumentation that is available or the fact that some people are quite competent in its use. I would suggest to the federal government that rather than trying to have everybody utilize this equipment, a selective approach is desirable both for the choice of the operator of the instrument and the accidents it is used for.

I would specifically suggest that for nuclear powerplants, rather than attempting to train large number of local monitors to make the necessary conversion for civil defense instrument readings, we should insist that the nuclear power plants have adequate staffing and instrumentation to make the initial (four (4) hours) environmental assessments. Most people agree that the initial decisions for protective actions have to be made based on information supplied from the facility. Further, we believe we can get people from the facility to make the necessary environmental measurements quicker and more accurately than we could get a policeman or fireman into the area to get his readings, then make the necessary correction, and hope that he has not forgotten his training. In fact, quite possibly we will have our policemen and firefighting forces engaged in protective actions activities which may be much more important than trying to teach them to read an instrument once every six (6) months. Further, because of instrumentation limitations, the more likely accidents, i.e., those involving milk and food supplies, will not be detected and may lead to initial reports that there is no problem when in fact a significant health problem exists. With radiation accidents, as with accidents involving hazardous chemicals, you do not need a volume of data to determine when and where you need to take a protective action. If we did, many more people would have already been killed by the many chemical accidents we have had in our country.

(II) Alabama continues to support the following resolutions of the Conference:

Year:	*Resolution No.*
1971	1–5
1972	2
1973	1
1974	None
1975	1
1976	1–2
August 1976	1–2

(III) Most of the reasons for calling for more federalization of radiation safety control are given in Number I. We feel that basically one agency should be responsible for all radioactive materials. This would include the licensing of the users, equipment, and the environmental discharges. Further, we feel either the same agency or a different agency should be responsible for the use of ionizing radiation use in the machines. This regulatory control over machine produced radiation would probably be best applied at the manufacturer in the case of the federal government and the user in the case of the state government. In either case provisions should be made for a state to fully participate in the program as a compliance unit. To do otherwise would result in a needless waste of trained resources. This is one of our prime objections to the current OSHA policy.

Currently when we report problems involving machine-produced ionizing radiation, it appears to get swallowed up in the great federal bureaucracy. Perhaps months later, we receive a telegram informing us that at long last a compliance program has been initiated which may last for years. In most cases the state is left powerless to encourage prompter compliance or even know what the details of the compliance program are. We suggest that all of this secrecy is really not necessary and that the states can and should be kept aware of compliance activities regarding this equipment. In many cases states will assist in identifying units remaining in noncompliance, and in most cases have been the initiators of noncompliance activities involving *ionizing* radiation.

One of the major dfficulties of any program is funding. The ability of a state to fund a radiological health program varies widely. We do not claim that all of the problems associated with state radiological health programs are funding related, however, a large number are. Generally those states which are Agreement States are better funded than Non-Agreement States. To encourage states to become Agreement States as well as to support those Agreement States currently in existence, we would suggest that legislation should be considered by Congress which would authorize and require a state to collect license fees for byproduct, source, and special nuclear licenses issued by that state as an agreement State. Such fees would be the same as those charged by the U.S. Nuclear Regulatory Commission and are considered a federal grant to the Agreement State for radiation health and safety purposes. Specifically the federal legislation should authorize the Agreement States to collect and use the fees. This would also equalize the economic disadvantage that currently exists for some operations in Non-Agreement States.

If you have any questions or wish to discuss these matters further, please contact me.

Sincerely,

AUBREY V. GODWIN,
Director, Division of Radiological Health.

COMMENTS SUBMITTED BY UNITED ACTION FOR ANIMALS, INC.

United Action for Animals, Inc. (UAA) submits these comments for inclusion in the record of the Committee's study of the biological effects of radiation. UAA is a membership organization committed to ending unneeded live animal experimentation because UAA believes that live animal experimentation is not a proper or effective way of determining health and safety standards for human beings.

As the testimony before this Committee has indicated, the public is interested in the biological effects of ionizing and non-ionizing radiation in the doses that occur in real life. Except in isolated instances, these are low-dose, chronic exposures. Yet radiation researchers continue to rely on the bombardment of animals, usually with high doses over a short term. The record of this Committee confirms that this method yields little if any information about the biological consequences of the "real life" problem.[1] The only certain product of most present radiation research is injury to thousands and thousands of animals who experience indescribable agony in the process.

In November 1975 Rep. George E. Brown, Jr., held week-long hearings on "The Costs and Effects of Chronic Exposure to Low-Level Pollutants in the Environment," including radiation. At that time, radiation research experts admitted that the cause of death in short-term high-dose radiation experiments "may not be the same" as in real-life low-dose chronic exposures. But only one witness urged the study of chronic doses relevant to the real world. Another witness expressed caution about trying to extrapolate from high to low dose, stating flatly that "we may never know the risk" from chronic low-dose exposure. But there was no consensus on the question of what is a reliable means for determining the radiation risk to humans in everyday situations.

It was the same story in hearings held a year later, in November 1976, by the House Committee on Interior and Insular Affairs, Chairman James A. Haley. There, two more witnesses testified that the biological effects of radiation at high doses are different from those resulting from reallife low-dose exposure levels. (Some scientists point out that high doses of anything overwhelm the body's metabolic pathways, rendering abnormal results.) Again, in these hearings, there was such scientific confusion about the biological effects of low-dose radiation that Dr. Roger Mattson of the Nuclear Regulatory Commission, asked, apparently in frustration: "How do we come to a consensus of scientific opinion of how to protect people from low levels of radiation?"

This, in spite of the fact that radiation research has been going on since the turn of the century.[2] Is it too much to suggest that continued use of live animals in experiments using old shop-worn techniques will not produce the breakthroughs so necessary to understanding the health problems of radiation?

Today's researchers, probably as a result of their education and training in animal research, downgrade the use of other research and testing methods, such as living cells, including human cells, growing and functioning in tissue culture.

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[1] See, e.g., testimony of Dr. Steven O. Schiff, June 16, p. 5; Dr. Erwin D. J. Bross, June 17, pp. 1–2.

[2] A review published in The Archives of Pathology (34:562) in 1942 on the biological effects of radiation on many species of animals cited references going back to 1903.

Yet in 1965, radiation experts, under sponsorship of the Atomic Energy Commission, published a book entitled "Mammalian Radiation Lethality," in which they described the use of tissue culture in radiation research as follows:

"Quantitative cellular radiobiology was advanced markedly by the introduction of single cell tissue culture techniques which allowed characterization of the radiation response of populations of mammalian cells, as well as individual cells in that population. Introduction of the technique allowed the demonstration, contrary to previous thought, that mammalian cells in tissue culture are comparable in their radiosensitivity to cells irradiated in the live animal. The method is unique in that an inoculum of growing tissue culture cells can be plated out on petri dishes; and if the dilution is sufficiently great, the overwhelming majority of visible colonies that appear in a matter of days will have been derived from, and therefore represent, the original single cells. Thus, following irradiation, the fate of an individual cell and its progeny can be determined accurately by counts of grossly visible colonies." (Mammalian Radiation Lethality, Academic Press, 1965.)

Animal researchers of course know that quantitative (numerically measurable) tissue culture methods exist, but apparently prefer the trial and error of the live animal experiments which are familiar to them. For example, at Rep. Brown's hearings in 1975, a researcher from Oak Ridge (ERDA) first stated:

"If we talk about dose levels where the probability of an effect is one in a thousand or one in a hundred thousand we simply cannot obtain the information from animal experiments for technical, logistical and economic reasons. The very low dose end of the curve, then, cannot be established by empirical observations."

Then he testified:

"It is possible to maintain and grow animal and human tissue cells outside the body in much the manner that bacteria can be grown in dishes of culture media. We know that certain carcinogens (cancer causing agents) can alter the characteristics of these cells so that when they proliferate to form colonies of cells the altered or "transformed" cells form colonies with characteristics that are different from untransformed cells. Furthermore, in some cases at least, these untransformed cells will produce tumors when inoculated into suitable test animals.[3] It would be possible, though technically difficult and tedious, to try to determine if a very small dose of carcinogen caused transformation in one cell in a hundred thousand or perhaps one cell in a million. In theory, at least, dose-response curves could be obtained down to very low levels of effect. The difficulty is that at present we do not know whether this system bears any relationship to what happens in the intact animal. . . . Theories must be consistent with observations at high dose levels."

Thus, despite the inadequacy of the old methods, he is right back where he started: the administration of high doses to animals without a hope of finding any answers.

Although animal researchers profess not to know what the production of cancer in tissue culture "means in animals," the animal of concern in environmental cancer is man. Human cells, obtainable commercially or from hospital surgical services, can be kept viable and functioning in vitro as per the method described by the Oak Ridge researcher. Both radiation and environmental chemicals can be tested on these living cells. The level of radiation (or concentration of environmental chemicals, such as pesticides) that "transforms" normal human cells into cancerous ones can be determined through the use of these living cells. But it only confounds these results to inject the cancerous human cells into foreign hosts—animals (in the 90-year old method that is still being used). Results in tissue culture can be seen within days instead of years, as in the case of live animals. That the method may be "to technical" or tedious"—especially for those trained in animal research—elevates form over substance by giving priority to the experiments and experimenters rather than the knowledge that is being sought.

A Dutch scientist has forcefully summarized the advantages of in vitro research methods:

"At present, only a few investigators use in vitro methods to study X-ray induced transformation [i.e., of normal cells to cancer]. This is unfortunate, because cell culture systems can be used to investigate malignant transformation directly at the cellular level with the exclusion of the interfering factors operating in whole animals.

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[3] [This is a 90-year old method. Editor's note].

"With these in vitro methods, it is possible to establish dose-response relationships for malignant transformations induced by single and split doses of X-rays and also for other types of radiation. This offers the possibility of obtaining better insight into the potentially carcinogenic effect of very low doses of radiation.

"Another important advantage of in vitro systems is that chemical and viral carcinogens can be introduced and investigated in the same system. This makes these systems suitable for the exploration of the fundamental mechanism of carcinogenesis." (Biology of Radiation Carcinogenesis, p. 301, Raven Press, N.Y., 1976.)

Additionally, there are numerous other modern research methods that are not being used. For example, scientists at Oak Ridge National Laboratory developed a mathematical model for the distribution and excretion of the radioactive element thorium (^{228}TH) and its decay product (^{224}Ra) and used the model to estimate the radiation doses to human organs and tissues from a single intake of thorium. Their model was based on data on humans and dogs reported in the experimental literature. Further, they were able to calculate radium retention in man over a 50-year period of time. (Bull. Math. Biol. 35:129, 1973). By contrast, institutions across the country are still gassing animals (mostly Beagle dogs) with radioactive materials such as plutonium to study the distribution of "hot particles" in the respiratory system.

Probably the most important advance of this century was recently reported. Researchers at private laboratories, under contract with the Environmental Protection Agency, developed a "mathematical prediction system for determining the toxicity of chemical compounds." Their method, based on "sophisticated statistical techniques," permits the predictions of toxicity of untested chemical compounds, now routinely determined in the so-called rat LD50 test (the lethal dose from which 50 percent of the animals must die). Their mathematical prediction system "could also be applied to . . . long-term tests, carcinogenicity, etc. in other species and for other routes of administration." [4]

With proper motivation and incentive, similar or related methods could—and should—be extended to radiation research; there is more than 70 years' data in the published literature to start with.

But only Congress can lead the way to the development of modern, sophisticated research methods in radiation research. We urge that the Committee recommend and prepare legislation to accomplish the following: the elimination of experiments that use old, well worn techniques or that duplicate and overlap other well documented research; the elimination of the use of laboratory animals to produce research results of dubious value and application to the study of human response to radiation of all sorts; and the promotion of research alternatives and the advancement of modern, sophisticated research methods through the use of substantial incentive awards to the research community.

Respectfully submitted,

ELEANOR SEILING, *President.*

APPENDIX TO COMMENTS OF UNITED ACTION FOR ANIMALS, INC.

EXAMPLES OF MODERN RESEARCH METHODS WHICH DO NOT REQUIRE THE USE OF LIVE ANIMALS

1. Gamma-Irradiated Heart Cells in Vitro
2. In Vitro Interactions (Synergism) of Chemical Carcinogenis and Radiation.
3. Radiation Damage and Repair.
4. Radiation Research with Nuclear "Phantoms".
5. Radiation Inhalation.
6. Biological Effects of Radioactive Material on Cultured Cells.

Gamma-irradiated heart cells in vitro.—Scientists at Harvard University used rat heart cells in vitro (outside the body) to study the effects of acute doses of gamma radiation in post-mitotic (after dividing) mamalian cell function. Hearts from 28 new-born rats were excised and kept alive and beating in suitable nutrient solutions. Seven days after "seeding" the culture cells, the scientists irradiated them at doses ranging from 1,000 to 100,000 rads with a cobalt–60 (Co) irradiator. Following irradiation, the heart cells were incubated at 98.6 F for the 30-day period of the experiment. The beating rate of the heart cells in each of the cultures was measured daily with a "heated state" inverted light microscope. Two or three days after irradiation, beating in those cultures receiving 50,000 or 100,000 rads became arrhythmic (i.e., stopped beating for a few seconds, then beat quickly for the next few). Doses of 50,000 and 100,000 rads completed inhibited the culture from beating within 8 to 23 days, "indicating the functional limit of radiation these cells can tolerate." Doses of 10,000 rad or less did not affect the beating rate or rhythmicity, "although the overall cell density appeared sparser than in control cultures." Conclusions: The beating of heart cells in vitro allowed the physiological expression of radiation damage to be numerically measured. Loss of rhythmicity after gamma-radiation occurred much earlier than the loss of the ability of the cells to contract spontaneously. An advantage of the in vitro method of irradiating cultured heart cells is that it "eliminates the effects of vascular (blood vessel) damage," so that direct radiation injury to the cells themselves can be studied. The scientists said, "Maintenance of these cells for periods longer than 30 days may aid in identifying functional effects after irradiation with lower doses." (Int. J. Radiat. Biol., 28(1) : 99–102, 1975)

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[4] A Toxicity Prediction System, developed by Genesee Computer Center, Inc., Rochester, N.Y. and Franklin Inst. Research Labs. Philadelphia, Pa., under partial sponsorship of the EPA, April 1977. Other techniques directly applicable to research in the radiation field are discussed in the appendix.

In vitro interactions (Synergism) of chemical carcinogenis and radiation.—Cancer toxicologists usually study the interaction of cancer-causing chemicals and radiation by dosing live animals with the chemicals and then irradiating them or vice versa. In contrast, a scientist at the National Cancer Institute used hamster cells to study this phenomenon. In addition to being "reproducible" and numerically measurable, the in vitro procedure for transforming normal mammalian cells into cancer cells "made possible the separation of events related to the process leading to transformation from secondary events that interfere with the early recognition of transformation." Exposure of the hamster cell strains to cancer-causing chemicals resulted in a dose-response relation which could be described mathematically by a "poisson distribution indicating that the transformation . . . is inductive [directly produced by the chemicals]." Pretreatment of the cells with ionizing radiation or "alkylating" chemicals (chemotherapeutic cancer drugs which in high doses are toxic to normal tissue) enhanced the frequency of transformation on a cell or colony basis "ordinarily obtained with known chemical carcinogens." Pretreatment with non-ionizing ultraviolet radiation did not have a similar effect. The two types of radiation and the alkylating agents reduced the efficiency of the cells to clone.

Radiation damage and repair.—Scientists at the University of Texas in Dallas used hamster lung cells in culture to study repair of radiation damage. Appropriate numbers of cells were plated onto petri dishes to yield about 200 colonies "in control and experimental dishes." The cells were than irradiated with x-rays at a dose selected to cause "potentially lethal" damage (i.e., damage which may be repairable to a non-lethal level if suitable conditions are provided). Immediately after exposure to a single radiation dose, cells were overlaid with either "FS–15" (complete growth medium) or "Earle's balanced salt solution." After a period of time in the balanced salt solution, buffer (the chemical balancing the solution) was discarded and cells were provided with FS–15 for colony formation. After 10 to 12 days of growth, cell colonies were counted. "Survival rapidly increased to a maximum after 1 hour in the balanced salt solution." This initial survival was followed by a decrease and then a second rise. "The initial increase observed . . . suggests that in the presence of buffer, mammalian cells repair potentially lethal damage." The subsequent fall in survival suggested that, during the repair process, an unstable cellular state occurred which prevented cell division in complete growth medium. Conclusion: A cellular environment which inhibits cell division is necessary if cells are to repair themselves following "potentially lethal" radiation damage. Further experiments on the cultured cells showed that their capacity for repair was also dependent on cell age. (Science, Vol. 165, Aug. 1, 1969)

Radiation Research with Nuclear "Phantoms".—Alderson Research Laboratories developed a life-like radiological test subject called "REMAB" (Railroad Equivalent Manikin-Absorption). These dummies or "phantoms" are equivalent to an average man in size and contours; they are filled with "a solution that has the same radiation-interaction properties as human soft tissues." REMAB was designed for radiation research and can be used for "depth-dose" measurements and "nuclear-accident re-creation." The dummies can be loaded with radioactive materials to determine the exposure effects to adjacent areas. ("Alderson Nuclear Phantoms," Alderson Research Laboratories, Inc., Stamford, Conn.)

Radiation Inhalation.—Over the past 30 years at institutions all across the country, animals have been forced to inhale radioactive materials. In contrast, scientists at Pacific Northwest Laboratories, under contract to the U.S. Atomic Energy Commission, designed a computer program that "permits rapid and consistent estimates of the effective radiation dose to the human respiratory tract and other organs resulting from the inhalation of radioactive aerosols." They also constructed mathematical models to describe the atomospheric dispersion of radioactive material "for the purpose of evaluating doses resulting from either accidental or chronic atmospheric releases of radionuclides." In the model, the respiratory tract was divided into three regions: the nasopharyngeal (nose-pharynx); the tracheobronchial (air passages to lungs; and the pulmonary (lung). The scientists employed "complex mathematics" to design the computer program input which consisted of several variables: duration of inhalation exposure, ventilation rate, time interval within which the dose is delivered, organs of interest, quantity of radionuclide inhaled, and "solubility class" and particle size. Output from the "CDC CYBER 74" computer consisted of the effective radiation dose to "any of 18 organs and tissues" in the human body. The model was extended "to include calculating organ doses resulting from chronic inhalation," as well as acute inhalation of radioactive particles. The scientists said that most of the basic data required to complete the calculations are available at "data libraries." The data in the libraries are set up such that "additional data or changes to existing data may be made with little difficulty." (BNWL–B–389 UC41, Dec., 1974).

Biological Effects of Radioactive Material on Cultured Cells.—Researchers at Rutgers University Agricultural Experiment Station are using cultured mammalian cells to test the damaging effects of tritium and other radioactive materials. They are conducting a comparative study of the chemical effects of radiation and of high energy, heavy ions (electrically charged atoms) and gamma rays on the isolated cells. Methods will be used to 'accurately" relate deposition and absorption of radioactive energy to biological damage. Though the work is still in progress, the scientists have already found "significant chemical differences between the effects of tritium beta rays and gamma rays." More interpretation is needed, but results so far are "potentially important since the present basis for tritium maximum permissible concentration assumes little difference between these radiations." (SSIE, Notice of Research Project, No. GY–C0353–4, July 1977)

UNIVERSITY OF OREGON HEALTH SCIENCES CENTER,
Portland, Oreg., June 13, 1977.

HON. WARREN G. MAGNUSON,
Chairman, The Senate Commerce Committee,
Russell Old Senate Office Building,
Washington, D.C.

DEAR SENATOR MAGNUSON: Your hearings on the adequacy of United States safety standards for microwaves and radiowaves are timely indeed. In recent years evidence has steadily mounted concerning the likelihood of low power level microwave cumulative dose effect hazards. It has also become apparent that certain federal agencies and private contractors have vested interests in obstructing the public scrutiny and adequate research support for accurate determination of the risks of these apparent hazards. Most people do not realize that certain types of non-ionizing radiation (e.g. microwaves and radiowaves) can have similar effects to the readily recognized dangers of ionizing radiation (X rays and gamma rays), with the principal difference being the much lower incidence of tissue damage due to the much lower energy content of the non-ionizing radiation. However, the lifetime accumulation of non-ionizing radiation dose, the damage to the posterior capsule of the ocular lens, and the suspicion of increased cancer risk are all characteristics in which the effects of non-ionizing radiation resemble those of ionizing radiation. The continuing rapid increase in use of radiowaves for military and civilian communication and sensor systems as well as the growing popularity of microwave cooking in the home, means that it is imperative to develop accurate and adequate health risk estimates from sources which cannot be accused of vested interest in health hazard information suppression. This will require epidemiologic and experimental research of a whole array of circumstances over considerable periods of time because of the intricate influence of environmental variables and the latent ueriod s between exposures and potential chronic disease manifestations.

A volunteer member of our faculty, Mr. William Bise, has been instrumental in bringing to our attention the fact that foreign scientists have gathered a great deal of evidence suggesting the existence of significant hazard from low level microwave radiation. He is an experienced radio broadcaster and has formed a non-profit corporation (Pacific Northwest Center for the Study of Non-Ionizing Radiation) for the purpose of promotion and support of investigation of these hazards. He is writing to you under separate cover. We endorse your efforts to look into this matter and anticipate the eventual facilitation of of radiowave health hazard investigation as a result.

Sincerely,

WM. E. MORTON, M.D., DrPH, *Professor*

PACIFIC NORTHWEST CENTER FOR THE STUDY OF NON-IONIZING RADIATION,
Portland, Oreg., June 6, 1977.

Hon. WARREN G. MAGNUSON,
U.S. Senate, Russell Senate Office Building, Washington, D.C.

DEAR SENATOR MAGNUSON: Enclosed is material that I would like to submit in lieu of verbal testimony in the upcoming senate subcommittee hearings on microwaves. In a telephone conversation with Sharon Nelson on Wednesday June 1, 1977, I pointed out that my limited budget does not allow me to appear in person. The material describes a pilot study of central nervous system radiofrequency (RF) effects which I conducted on ten human volunteers at a power level on the order of 67 microvolts per meter intensity, previous to founding a non-profit research corporation. As you know, Public Law 90–602 set the so called safe level for human exposure to this energy at about 195 volts per meter. The pilot study findings suggest that brain waves (and possibly behavior) are affected at specific frequencies at substantially lower power levels of RF than people can be exposed to in their daily lives. Whereas further research is necessary to verify or deny the pilot study findings, it is my opinion that a meaningful risk factor already exists for the population at large. The technical paper entitled Radiofrequency Induced Interference Responses in the Human Nervous System has been submitted for consideration in the upcoming URSI International Symposium on Biological Effects of Electromagnetic Waves to be held at Airlie, Virginia on October 30–November 4, 1977. Also enclosed is a popular technical article that I authored which describes the pilot study which appeared (without references) in the January 1977 issue of Communications/Engineering Digest.

I have worked out an experimental design using the ambient RF as a signal source for a follow up study. The design conforms to all H.E.W. guidelines for protection of human subjects. If funds can be granted for this research, many questions concerning RF biological hazards can be answered.

Electronics engineers are dedicated to designing, building and maintaining better and ever more sophisticated products for radiating and detecting all kinds of electromagnetic waves. With the exception of careful respect for high voltages, currents and power, a good engineer will insist that low power microwaves or radiowaves cannot possibly affect human behavior and/or health. As an engineer who held that view for fourteen years, I can attest to this fact. Except for a rather dramatic incident in 1970 involving my wife, who was nearby while I was troubleshooting some gear with a low power microwave generator, I might not have done a pilot study of RF effects; and I might still have remained unconvinced that low level microwaves/radiowaves are hazardous at specific frequencies.

Since I became a clinical instructor in environmental medicine at the University of Oregon Health Sciences Center, it has become apparent to me that most physicians are unaware that low-level radiowave biological effects can mimic many symptoms of various defined diseases. I have found the entire subject of radiowave hazards very unpopular to science, business, industry and the military; perhaps because recognizing these hazards would cause so many necessary changes in these various areas.

An international radiowave conflict has been going on for some time and was intensified dramatically in July 1976 with the addition of the Soviet 10 Hz pulses which may produce serious biological effects on people regardless of the real intent of these intense pulses of radiant energy. It is not necessary for nations to declare war of this nature since it is silent and invisible to our normal senses.

Using the legal power limit of 10 milliwatt per square centimeter, a malicious person could easily build (or buy surplus) equipment that could physically and mentally damage people, over a period of time, without the victim ever knowing what was happening to him. The members of the executive, legislative and judicial branches of government may even be more vulnerable to this kind of personal harassment than the ordinary citizen.

It is conceivable that special interest groups have already resorted to tactics of this nature. I was called as a consultant in April of 1976 in a case in Seattle, Washington where the microwaves and lasers which my instruments detected possibly were the result of personal harassment. One motive could be the desire to buy property at bargain prices from people who are anxious to sell in order to leave the neighborhood because they no longer feel well in their home or business. Because I was working alone in Seattle, my findings remain inconclusive. Military radar scatter also seemed to be one of the sources of radiation in the two different areas which I checked.

To paraphrase an engineer formerly with the North American Air Defense Command, "You'd never really know the cause of death from this stuff . . . . you could hit someone, coagulate their blood and no one would ever know what happened."

I hope that there is something that your committee can elicit from the upcoming hearings to at least inform, if not protect, the people of the United States from electromagnetic hazards. The specialization of science unfortunately limits the scientists' ability to bridge the interdisciplinary gap necessary to realize the urgent need for a joint effort of investigation into low power level microwave hazards.

There is another serious matter which involved a breach of security in Seattle concerning the President's "Doomsday" airplane. If at any time you might wish to talk to me, please let me know.

Sincerely,

WILLIAM BISE.

Enclosures.

RADIOFREQUENCY INDUCED INTERFERENCE RESPONSES IN THE HUMAN NERVOUS SYSTEM

(By William Bise)

Summary: Interest in lowpower athermal RF effects on biological systems has grown in recent years among American researchers and the foreign literature on the subject is prolific. Against this background a pilot study was conducted on five men and five women volunteers. Participants in a group of eight experiments completed from July 1975 through June 1976 were, of necessity, highly preselected. They ranged in age from 18 to 48 years. Three had been occupationally exposed to RF energy; the other seven had not and all were in apparent

good health. The RF ranges covered from .1 to 960 Mhz CW and 8.5 to 9.6 Ghz pulse modulated. Power levels were varied from 10^{-16} wt/cm^2 to 10^{-13} wt/cm^2. Three variable frequency low power output test alignment generators served as signal sources. Subjects were seated and oriented so that they could not see the equipment or the operator. During data gathering they did not know to what frequencies the sources were tuned nor did they know when the signal source was off or on. A 1 meter free space impedance coupled antenna was placed parallel to and 1 meter from the upper torso and head during CW tests. The open wave guide output of the pulse modulated source was oriented 1 meter from and perpendicular to the sternum. Any changes in the EEG traces were photographed from a cathode ray tube display and/or note was taken of the frequency which produced them. Previous to irradiation, the normal EEG tracings of the subjects were noted or photographed. Experimental time for each volunteer was typically 50 minutes. Tests were done at different times of the day at various locations, both in and out of a Faraday room. Signal source accuracy and power output levels, at the subject to antenna distance, were measured with two spectrum analyzers.

The EEG instrumentation used gave sequential recording of a single trace from an electrode pair and was specially designed for use in RF fields. Artifacts were identified and controlled out of the tests. Pushbutton switchable selectivity allowed sampling from the three different cranial areas without changing electrode placement. Plastic covered skin surface type electrodes were used.

Subjects' EEG traces displayed desynchronized alpha waves of 15 to 25 percent higher than normal amplitude and slow waves appeared at certain radiofrequencies. Conversely, diminution and desynchronization of alpha wave amplitude on the order of 20 to 50 percent occurred at other radiofrequencies and 2 to 6 Hz slow waves appeared. These two anomalous patterns were found in both men and women volunteers. Mental attitudes appeared to change during the tests. CW frequencies at a power density of about 10–15 wt/cm.^{2} which produced EEG changes in males, were found between 130 and 780 Mhz. Female volunteers' EEG alterations occurred between 350 and 960 Mhz. Pulse modulation tests on two males, at a power density of about 10-12 wt/cm ^{2} showed EEG changes around 9.1 and 9.15 Ghz. Brain waves changed almost immediately upon tuning a generator to a frequency which produced them and then almost immediately reverted to their normal patterns when the generator frequency was altered or turned off. Various lead configurations and antenna orientations were tried during the CW tests and demonstrated that active sampling from the right frontal parietal to the right occipital, with antenna presented 1 meter from left hemisphere, yielded repeatable results. This suggests that the right hemisphere is the more responsive one to RF energy. Experiments performed near noon and midnight showed the most significant EEG pattern changes thus a circadian biorhythm dependence may be involved.

Notably, the CW RF energy of about 67 microvolts per meter which was seen to alter brain waves is characteristic of the average EEG voltage level which exists at the surface of the head. The EEG changes seen in most of the participants were produced by this RF energy level at frequencies between 130 and 960 Mhz. Since most researchers agree that the relaxation frequency of protein bound water must lie between 100 and 1,000 Mhz, it is possible that resonance absorptions occurred. The shape of the human head (spherical antenna bandwidth), the piezoelectric characteristic of bone and the possible up and down frequency shifts of radio energy entering and leaving protein bound water in near surface tissue are considerations in this phenomenon. Altered EEG patterns resulting from electrical stimuli should be expected to reflect corresponding behavior changes. It is known that both the thalamus and hypothalamus are especially sensitive in this respect. The 6 Hz waves which appeared in some subjects' EEG patterns are similar to those waves associated with annoyance seen in earlier EEG research. Brain wave changes were triggered in alert volunteers by external energies which they could not perceive. At very low RF field densities the body's neurointegrative systems evidently do not function normally or somehow may be prevented from normal functioning. RF induced stimulation of the midbrain structures may be a fundamental factor. The full impact on biological systems of long exposure to low intensity RF energy is not known, but the likelihood of cumulative dose effects means that small doses are important.

MEDICAL COLLEGE OF VIRGINIA,
VIRGINIA COMMONWEALTH UNIVERSITY,
Richmond, Va., July 25, 1977.

HON. WENDELL H. FORD,
HON. ADLAI E. STEVENSON,
Committee on Commerce, Science, and Transportation,
U.S. Senate,
Washington, D.C.

DEAR SENATORS FORD AND STEVENSON: I am writing to you in reference to the U.S. Senate Committee on Commerce, Science, and Transportation hearings concerning the current status of health protection problems from radiation exposure. I have been involved in research related to the biological effects of ionizing and nonionizing radiation for the past twenty years and much of my research has been directed toward the establishment of safe exposure levels for humans.

My particular interest is the biological effects of microwave radiation, a topic that as you know is now much in the public view and presents a number of controversial aspects. In spite of the fact that recent research in this area has revealed a number of physiological and psychological alterations in various species of experimental animals, research support for such studies has been rather drastically reduced in the past few months. I fully realize that biologic effects of microwave exposure are but one of the many problems related to radiation exposure, but it is of great concern to me personally as a scientist and as a citizen, that sustained research support does not appear to be forthcoming for the solution of problems such as this. I believe we need answers now for the questions that will inevitably arise in the near future due to the ever increasing levels of occupational and nonoccupational exposure to microwave and radiofreqency radiation. Such answers can only be obtained by sustained research efforts which are difficult, if not impossible, in the face of drastic fluctuations in research support in areas such as this.

My views are based upon the results of research being conducted in my laboratory as well as a rather extensive review I have recently completed of the literature in this area. The results of this review are detailed in the enclosed article entitled "Biological Effects of Microwave and Radiofrequency Radiation." In view of the extent of this review article I would like to summarize a few of what I feel are the most salient points regarding human exposure to microwave and radiofrequency radiation:

(*a*) a significant number of studies conducted during the past six years in this country and the Soviet-bloc nations have revealed various physiological and psychological alterations in living systems at levels in the region of 10 mW/cm^2, the human occupational exposure standard in effect in the United States,

(*b*) although microwave-induced heating appears to play a role in the induction of such effects, there are qualitative and quantitative differences in the radiation effects compared to nonradiation heating,

(*c*) the reported effects of exposure of normal, healthy animals to low-intensity (ca 10 mW/cm^2) fields by and large appear to be reversible in nature, but chronic exposure (i.e. periods of weeks or months) results in immunological alterations suggesting that exposure of animals compromised by coincident exposure to, for example, pathogenic organisms or drugs may result in significantly enhanced effects. Multiple-stress microwave interactions could present a wide spectrum of problems in human populations due to endemic viral and bacterial pathogens and to the prevalence of drug usage. Although studies to ascertain the significance of such interactions have been proposed, such investigations are currently suffering from a lack of funding.

((*d*) In spite of the evidence indicating that low-intensity microwave and modulated radiofrequency and low frequency electromagnetic fields alter biological systems, the presently available data is not sufficient to enable basic interaction mechanisms to be determined.

I believe that the biological effects of electromagnetic fields pose significant problems that must be solved if we are to preserve the quality of our environment. Research in this area is for the first time beginning to define the true nature of the problem and it is also providing the data needed for the future development of exposure guidelines that will prevent deleterious effects. I urge you, therefore, to consider the necessity of supporting efforts for the funding of sustained research in this area.

I thank you for your interest in this matter and will willingly provide any additional information at my disposal to aid in your deliberations.

Very truly yours,

STEPHEN F. CLEARY, Ph.D.,
Professor of Biophysics,
Medical College of Virginia.